PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Greenberg, et. Al.	**Art Unit:**	Unassigned
Serial No.:	Unknown	**Examiner:**	Unknown
Filed:	Herewith		
Docket No.:	S100DIV1		
For:	Retinal Color Prosthesis for Color Sight Restoration		

Assistant Commissioner
For Patents
Washington, D.C. 20231

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October 12, 2001

Emily M. Stuart

PRELIMINARY AMENDMENT

Dear Sir:

Please amend the above-identified patent application as follows:

In the Specification:

Please replace the title with:

Package for an Implantable Medical Device

Please add:

Cross Reference to Related Applications

This application is a division of US Application 09/515,383, filed February 29, 2000, entitled Retinal Color Prosthesis for Color Sight Restoration, which claims priority of US Provisional Application 60/125,873, filed March 24, 1999, entitled Method and Apparatus for Sight Restoration.

Please amend the first full paragraph on page 3 to read as follows:

Subsequently, Michelson (U.S. Patent No. 4,628,933), Chow (U.S. Patent Nos. 5,016,633; 5,397,350; 5,556,423), and De Juan (U.S. Patent No. 5,109,844) all were issued patents relating to a device for stimulating undamaged retinal cells. Chow and Michelson made use of photodiodes and electrodes. The photodiode was excited by incoming photons and produced a current at the electrode.

Please amend the third full paragraph on page 3 to read as follows:

Najafi, et al., (U.S. Patent No. 5,314,458), disclosed an implantable silicon-substrate based microstimulator with an external device which could send power and signal to the implanted unit by RF means. The incoming RF signal could be decoded and the incoming RF power could be rectified and used to run the electronics.

Please amend the fourth full paragraph on page 3 to read as follows:

Difficulties can arise if the photoreceptors, the electronics, and the electrodes all tend to be mounted at one place. One issue is the availability of sufficient area to accommodate all of the devices, and another issue is the amount of power dissipation near the sensitive retinal cells. Since these devices are designed to be implanted into the eye, this potential overheating effect is a serious consideration.

Please amend the first full paragraph on page 4 to read as follows:

A desirable property of a retinal prosthetic system is making it possible for a physician to make adjustments on an on-going basis from outside the eye. One way of doing this would have a physician's control unit, which would enable the physician to make adjustments and monitor the eye condition. An additional advantageous feature would enable the physician to perform these functions at a remote location, e.g., from his office. This would allow one physician to remotely monitor a number of patients remotely without the necessity of the patient coming to the office. A patient could be traveling distantly and obtain physician monitoring and control of the retinal color prosthetic parameters.

Please amend the last paragraph on page 4 and continuing on page 5 to read as follows:

By having a method and apparatus for the physician and the technician to initially set up and measure the internal activities and adjust these, the patient's needs can be better accommodated. The opportunity exists to measure internal activity and to allow the physician, using his judgment, to adjust settings and controls on the electrodes. Even the individual electrodes would be adjusted by way of the electronics controlling them. By having this done remotely, by remote means either by telephone or by the Internet or other such, it is clear that a physician would have the capability to intervene and make adjustment as necessary in a convenient and inexpensive fashion, to serve many patients.

Please amend the first through the fourth full paragraphs on page 12 to read as follows:

Figure 11c shows a variation of a form of the elongated electrode wherein the electrode is thinner and more recessed from the well sides;

Figure 11d shows a variation of a form of the elongated electrode wherein the electrode is squatter but recessed from the well sides;

Figure 11e shows a variation of a form of the elongated electrode wherein the electrode is a mushroom shape with the sides of its tower recessed from the well sides and its mushroom top above the oxide insulating material;

Figure 12a shows the coil attachment to two different conducting pads at an electrode node;

Please amend the eleventh through the twelfth full paragraphs on page 13 to read as follows:

Figure 19 shows the physician's remote controller that has the same functionality inside as the physician's controller but with the addition of communication means such as telemetry or telephone modem; and

Figure 20 shows the patient's controller unit.

Please amend the first full paragraph on page 14 to read as follows:

Functionally, there are three main parts to an embodiment of this retinal color prosthesis invention. See Figure 1a. Figure 1a is oriented toward showing the main structural parts and subsystems, with a dotted enclosure to indicate a functional intercommunications aspect. The first part of the embodiment is external (1) to the eye. The second part is implanted internal (2) to the eye. The third part is means for communication between those two parts (3). Structurally there are two parts. One part is external (1) to the eye and the other part (2) is implanted within the eye. Each of these structural parts contains two way communication circuitry for communication (3) between the internal (2) and external (1) parts.

Please amend the last paragraph on page 14 and continuing on page 15 to read as follows:

Examining further the embodiment of the subsystems of the external part, see Figure 1b. These include an external color imager (111), an eye-motion compensation system (112), a head-motion compensation system (131), a processing unit (113), a patient's controller (114), a physician's local controller (115), a physicians hand-held palm-size pocket-size unit (130), a physician's remote controller (117), and a telemetry means (118). The color imager is a color video camera such as a CCD or CMOS video camera. It gathers an image approximating what the eyes would be seeing if they were functional.

Please amend the last paragraph on page 15 and continuing on page 16 to read as follows:

Color information (See Figure 2a), in the first preferred embodiment, is encoded by time sequences of pulses (201) separated by varying amounts of time (202), and also with the pulse duration being varied in time (203). The basis for the color encoding is the individual color code reference (211 through 217). The electrodes stimulate the target cells so as to create a color image for the patient, corresponding to the original image as seen by the video camera, or other imaging means. Using temporal coding of electrical stimuli placed (cf. Figure 2b, 220, Figure 2c, 230) on or near the retina (Figure 2b and Figure 2c, 221, 222) the perception of color can be created in patients blinded by outer retinal degeneration. By sending different temporal coding schemes to different electrodes, an image composed of more than one color can be produced. Figure 2 shows one stimulation protocol. Cathodic stimuli (202) are below the zero plane (220) and anodic stimuli (203) are above. All the stimulus rates are either "fast" (203) or "slow" (202) except for green (214), which includes an intermediate stimulus rate (204). The temporal codes for the other colors are shown as Red (211), as Magenta (212), as Cyan (213), as Yellow (215), as Blue (216), as Neutral (217). This preferred embodiment is directed toward electrodes which are less densely packed in proximity to the retinal cells.

Please amend the first full paragraph on page 16 to read as follows:

Color information, in a second preferred embodiment, is sent from the video data processing unit to the electrode array, where each electrode has been determined by test to stimulate one of a bipolar type: red-center green-surround, green-center-red-surround, blue-center-yellow-surround, or yellow-center-blue-surround. In this embodiment, electrodes which are small enough to interact with a single cell, or at most, a few cells are placed in the vicinity of individual bipolar cells, which react to a stimulus with nerve pulse rates and nerve pulse structure (i.e., pulse duration and pulse amplitude). Some of the bipolar cells, when electrically, or otherwise, stimulated, will send red-green signals to the brain. Others will send yellow-blue signals. This refers to the operation of the normal retina. In the normal retina, red or green color photoreceptors (cone cells) send nerve pulses to the red-green bipolar cell which then pass some form of this information up to the ganglion cells and then up to the visual cortex of the brain. With small electrodes individual bipolar cells can be excited in a spatial, or planar, pattern. Small electrodes are those with tip from 0.1 μm to 15 μm, and which individual electrodes are spaced apart from a range 8 μm to 24 μm, so as to approximate a one-to-one correspondence with the bipolar cells. The second preferred embodiment is oriented toward a more densely packed set of electrodes.

Please amend the first full paragraph on page 17 to read as follows:

Regardless of a particular theory of color vision, the impinging of colored light on the normal cones, and possibly rods, give rise in some fashion to the perception of color, i.e., multi-spectral vision. In the time-pulse coding color method, above, the absence of all, or sufficient, numbers of working cones (and rods) suggests a generalization of the particular time-pulse color encoding method. The generalization is based on the known, or partly known, neuron conduction pathways in the retina. The cone cells, for example, signal to bipolar cells, which in turn signal the ganglion cells. The original spatial-temporal-color (including black, white) scheme for conveying color information as the cone is struck by particular wavelength photons is then transformed to a patterned signal firing of the next cellular level, say the bipolar cells, unless the cones are absent or don't function. Thus, this second level of patterned signal firing is what one wishes to supply to induce the perception of color vision.

Please amend the second full paragraph on page 17 to read as follows:

The secondary layer of patterned firing may be close to the necessary primary pattern, in which case the secondary pattern (**S**) may be represented as **P** *(1 + ∈). The * indicates matrix multiplication. **P** is the primary pattern, represented as a matrix

$$\mathbf{P} = \begin{bmatrix} p_{11} & p_{1j} \\ p_{k1} & p_{kj} \end{bmatrix}$$

where **P** represents the light signals of a particular spatial-temporal pattern, e.g., flicker signals for green. The output from the first cell layer, say the cones, is then **S**, the secondary pattern. This represents the output from the bipolar layer in response to the input from the first (cone) layer. If **S= P*(1+∈)**, where **1** represents a vector and ∈ represents a small deviation applied to the vector **1**, then **S** is represented by **P** to the lowest order, and by **P*(1+∈)** to the next order. Thus, the response may be seen as a zero order effect and a first order linear effect. Additional terms in the functional relationship are included to completely define the functional relationship. If **S** is some non-linear function of **P**, finding **S** by starting with **P** requires more terms then the linear case to define the bulk of the functional relationship. However, regardless of the details of one color vision theory or another, on physiological grounds **S** is some function of **P**. As in the case of fitting individual patients with lenses for their glasses, variations of parameters are expected in fitting each patient to a particular temporal coding of electrical stimuli.

Please amend the first full paragraph on page 18 to read as follows:

As cited above, Greenberg (1998), indicates that electrical and photonic stimulation of the normal retina operate via similar mechanisms. Thus, even though electrical stimulation of a retina damaged by outer retinal degeneration is different from the electrical stimulation of a normal retina, the temporal relationships are expected to be analogous.

Please amend the second full paragraph on page 18 to read as follows:

To explain this, it is noted that electrical stimulation of the normal retinal is accomplished by stimulating the photoreceptor cells (including the color cells activated differentially according to the color of light impinging on them). For the outer retinal degeneration, it is precisely these photoreceptor cells which are missing. Therefore, the electrical stimulation in this case proceeds by way of the cells next up the ladder toward the optic nerve, namely, the bipolar cells.

Please amend the fourth full paragraph on page 18 to read as follows:

In Figure 2, which is extrapolated from external-to-the-eye electrical stimulation data of Young (1977) and from light stimulation data of Festinger, Allyn, and White (1971), there is shown data that would be applicable to the photoreceptor cells. One may scale the data down based on the ratio of the photoreceptor time constant (about 20 milliseconds) to that of the bipolar cells (about 9 milliseconds). Consequently, 50 milliseconds on the time scale in Figure 2 now corresponds to 25 milliseconds. Advantageously, stimulation rates and duration of pulses, as well as pulse widths may be chosen which apply to the electrode stimulation of the bipolar cells of the retina.

Please amend the first full paragraph on page 19 to read as follows:

In one aspect of an embodiment (Figure 1b), light amplitude is recorded by the external imager (111) . The video data processing unit uses a logarithmic encoding scheme (113) to convert the incoming light amplitudes into the logarithmic electrical signals of these amplitudes (113). These electrical signals are then passed on by telemetry (118), (121), to the internal implant (121) which results in the retinal cells (120) being stimulated via the implanted electrodes (121), in this embodiment as part of the internal implant (121). Encoding is done outside the eye, but may be done internal to the eye, with a sufficient internal computational capability.

Please amend the last paragraph on page 19 and continuing on page 20 to read as follows:

The retinal prosthesis system contains a color imager (Figure 1b, 111) such as a color CCD or CMOS video camera. The imaging output data is typically processed (113) into a pixel-based format compatible with the resolution of the implanted system. This processed data (113) is then associated with corresponding electrodes and amplitude and pulse-width and frequency information is sent by telemetry (118) into the internal unit coils, (311), (313), (314) (see Figure 3a). Electromagnetic energy, is transferred into and out from an electronic component (311) located internally in the eye (312), using two insulated coils, both located under the conjunctiva of the eye with one free end of one coil (313) joined to one free end of the second coil (314), the second free end of said one coil joined to the second free end of said second coil. The second coil (314) is located in proximity to a coil (311) which is a part of said internally located electronic component, or, directly to said internally located electronic component (311). The larger coil is positioned near the lens of the eye. The larger coil is fastened in place in its position near the lens of the eye, for example, by suturing. Figure 3b represents an embodiment of the telemetry unit temporally located near the eye, including an external temporal coil (321), an internal (to the eye) coil (314), an external-to-the-eye electronic chip (320), dual coil transfer units (314, 323), (321, 322) and an internal-to-the-eye electrode array (325). The advantage of locating the external electronics in the fatty tissue behind the eye is that there is a reasonable amount of space there for the electronics and in that position it appears not to interfere with the motion of the eye.

Please amend the second full paragraph on page 20 to read as follows:

For the light modulation (Figure 3d) case, a light emitting diode (LED) or laser diode or other light generator (361), capable of being modulated, acts as the information transmitter. Information is transferred serially by modulating the light beam, and energy is extracted from the light signal after it is converted to electricity. A photo-detector (362), such as a photodiode, which turns the modulated light signal into a modulated electrical signal, is used as a receiver. A set of a photo-generator and a photo-detector are on the implant (121) and a set is also external to the eye.

Please amend first full paragraph on page 21 to read as follows:

The internal-to-the eye implanted part shows a coil (551), which connects to both a rectifier circuit (552) and to a demodulator circuit (553). The demodulator connects to a switch control unit (554). The rectifier (552) connects to a plurality of diodes (555) which rectify the current to direct current for the electrodes (556); the switch control sets the electrodes as on or off as they set the switches (557). The coils (408) and (551) serve to connect inductively the internal-to-the-eye (500) subsystem and the external-to-the patient (400) subsystem by electromagnetic waves. Both power and information can be sent into the internal unit. Information can be sent out to the external unit. Power is extracted from the incoming electromagnetic signal and may be accumulated by capacitors connected to each electrode or by capacitive electrodes themselves.

Please amend first full paragraph on page 23 to read as follows:

Figure 10c shows an embodiment with the iridium slug as in Figure 10b, however, the top of the iridium slug (1011) is recessed below the level of the insulator; Figure 10d indicates an embodiment with the iridium slug (1011) coming to a point and insulation along its sides (1021), as well as a being within the overall insulation structure (1021). Figure 10e indicates an embodiment of a method for fabricating the iridium electrodes. On a substrate (1013) of silicon, an aluminum pad (1022) is deposited. On the pad, the conductive adhesive (1023) is laid and platinum or iridium foil (1024) is attached thereby. A titanium ring (1025) is placed, sputtered, plated, ion implanted, ion beam assisted deposited (IBAD) or otherwise attached to the platinum or iridium foil (1024). Silicon carbide, diamond-like coating, silicon nitride and silicon oxide in combination, titanium oxide, tantalum oxide, aluminum nitride, aluminum oxide or zirconium oxide (1012) or other insulator can adhere better to the titanium (1025) while it would not otherwise adhere as well to the platinum or iridium foil (1024). The depth of the well for the iridium electrodes ranges from 0.1 μm to 1 mm.

Please amend the last paragraph on page 23 and continuing on page 24 to read as follows:

Another aspect of an embodiment of the invention is the elongated electrode, which are designed to stimulate deeper retinal cells, in one embodiment, by penetrating the retina. By getting closer to the target cells for stimulation, the current required for stimulation is lower and the focus of the stimulation is more localized. The lengths chosen are 100 microns through 500 microns, including 300 microns. Figure 8c is a rendering of an elongated epiretinal electrode array with the electrodes shown as pointed electrical conductors (820), embedded in an electrical insulator (818), where the elongated electrodes (817) contact the retina in a conformal manner, however, penetrating into the retina (814).

Please amend the first full paragraph of page 24 to read as follows:

These elongated electrodes, in an aspect of this of an embodiment of the invention may be of all the same length. In a different aspect of an embodiment, they may be of different lengths. Said electrodes may be of varying lengths (Figure 8, 817), such that the overall shape of said electrode group conforms to the curvature of the retina (814). In either of these cases, each may penetrate the retina from an epiretinal position (Figure 8a, 811), or, in a different aspect of an embodiment of this invention, each may penetrate the retina from a subretinal position (Figure 9b, 817).

Please amend the last paragraph on page 24 and continuing on page 25 to read as follows:

Figure 11 (a-e) demonstrates a preferred structure of, and method of, making, spiked and mushroom platinum electrodes. Examining Figure 11a, one sees the support for the flat electrode (1103) and other components such as electronic circuits (not shown) on the silicon substrate (1101). An aluminum pad (1102) is placed where an electrode or other component is to be placed. In order to hermetically seal-off the aluminum and silicon from any contact with biological activity, a metal foil (1103), such as platinum or iridium, is applied to the aluminum pad (1102) using conductive adhesive (1104). Electroplating is not used since a layer formed by electroplating, in the range of the required thinness, has small-scale defects or holes which destroy the hermetic character of the layer. A titanium ring (1105) is next placed on the platinum or iridium foil (1103). Normally, this placement is by ion implantation, sputtering or ion beam assisted deposition (IBAD) methods. Silicon carbide, diamond-like coating, silicon nitride and silicon oxide in combination, titanium oxide, tantalum oxide, aluminum nitride, aluminum oxide or zirconium oxide (1106) is placed on the silicon substrate (1101) and the titanium ring (1105). In one embodiment, an aluminum layer (1107) is plated onto exposed parts of the titanium ring (1105) and onto the silicon carbide, diamond-like coating, silicon nitride and silicon oxide in combination, titanium oxide, tantalum oxide, aluminum nitride, aluminum oxide or zirconium oxide (1106). In this embodiment, the aluminum (1107) layer acts as an electrical conductor. A mask (1108) is placed over the aluminum layer (1107).

Please amend the first full paragraph on page 25 to read as follows:

In forming an elongated, non-flat, electrode (Figure 11b), platinum is electroplated onto the platinum or iridium foil (1103). Subsequently, the mask (1108) is removed and insulation (1110) is applied over the platinum electrode (1109).

Please amend the second full paragraph on page 25 to read as follows:

In Figure 11c, a platinum electrode (1109) is shown which is more internal to the well formed by the silicon carbide, diamond-like coating, silicon nitride and silicon oxide in combination, titanium oxide, tantalum oxide, aluminum nitride, aluminum oxide or zirconium oxide and its titanium ring. The electrode (1109) is also thinner and more elongated and more pointed. Figure 11d shows a platinum electrode formed by the same method as was used in Figures 11a, 11b, and 11c. The platinum electrode (1192) is more internal to the well formed by the silicon carbide, diamond-like coating, silicon nitride and silicon oxide in combination, titanium oxide, tantalum oxide, aluminum nitride, aluminum oxide or zirconium oxide and its titanium ring as was the electrode (1109) in Figure 11c. However it is less elongated and less pointed.

Please amend the third full paragraph on page 25 to read as follows:

The platinum electrode is internal to the well formed by the silicon carbide, diamond-like coating, silicon nitride and silicon oxide in combination, titanium oxide, tantalum oxide, aluminum nitride, aluminum oxide or zirconium oxide and its titanium ring; said electrode whole angle at it's peak being in the range from 1° to 120°; the base of said conical or pyramidal electrode ranging from 1 micron to 500 micron; the linear section of the well unoccupied by said conical or pyramidal electrode ranging from zero to one-third.

Please amend the first full paragraph on page 26 to read as follows:

Information transmitted electromagnetically into or out of the implanted retinal color prosthesis utilizes insulated conducting coils so as to allow for inductive energy and signal coupling. Figure 12b shows an insulated conducting coil and insulated conducting electrical pathways, e.g., wires, attached to substrates at what would otherwise be electrode nodes, with flat, recessed metallic, conductive electrodes (1201). In referring to wire or wires, insulated conducting electrical pathways are included, such as in a "two-dimensional" "on-chip" coil or a "two-dimensional" coil on a polyimide substrate, and the leads to and from these "two-dimensional" coil structures. A silicon carbide, diamond-like coating, silicon nitride and silicon oxide in combination, titanium oxide, tantalum oxide, aluminum nitride, aluminum oxide or zirconium oxide (1204) is shown acting as both an insulator and an hermetic seal. Another aspect of the embodiment is shown in Figure 12d. The electrode array unit (1201) and the electronic circuitry unit (1202) can be on one substrate, or they may be on separate substrates (1202) joined by an insulated wire or by a plurality of insulated wires (1203). Said separate substrate units can be relatively near one another. For example, they might lie against a retinal surface, either epiretinally or subretinally placed. Two substrate units connected by insulated wires may carry more electrodes than if only one substrate with electrodes was employed, or it might be arranged with one substrate carrying the electrodes, the other the electronic circuitry. Another arrangement has the electrode substrate or substrates placed in a position to stimulate the retinal cells, while the electronics are located closer to the lens of the eye to avoid heating the sensitive retinal tissue.

Please amend the second full paragraph of page 26 to read as follows:

In all of the Figures 12a, 12b, and 12c, a coil (1205) is shown attached by an insulated wire. The coil can be a coil of wire, or it can be a "two dimensional" trace as an "on-chip" component or as a component on polyimide. This coil can provide a stronger electromagnetic coupling to an outside-the-eye source of power and of signals. Figure 12c shows an externally placed aluminum (conductive) trace instead of the electrically conducting wire of Figure 12d. Also shown is an electrically insulating adhesive (1208) which prevents electrical contact between the substrates (1202) carrying active circuitry (1209).

Please amend the first full paragraph of page 27 to read as follows:

All structures, which are subject to corrosive action as a result of being implanted in the eye, or, those structures which are not completely biocompatible and not completely safe to the internal cells and fluids of the eye require hermetic sealing. Hermetic sealing may be accomplished by coating the object to be sealed with silicon carbide, diamond-like coating, silicon nitride and silicon oxide in combination, titanium oxide, tantalum oxide, aluminum nitride, aluminum oxide or zirconium oxide. These materials also provide electrical insulation. The method and apparatus of hermetic sealing by aluminum and zirconium oxide coating is described in U. S. Patent Application, Serial Number 08/994,515, now U.S. Patent No. 6,043,437. The methods of coating a substrate material with the hermetic sealant include sputtering, ion implantation, and ion-beam assisted deposition (IBAD).

Please amend the second full paragraph on page 27 to read as follows:

Another aspect of an embodiment of the invention is hermetically sealing the silicon chip (1301) by placing it in a metal or ceramic box (1302) of rectangular cross-section with the top and bottom sides initially open (Figure 13). The box may be of one (1302) of the metals selected from the group comprising platinum, iridium, palladium, gold, and stainless steel. Solder balls (1303) are placed on the "flip-chip", i.e., a silicon-based chip that has the contacts on the bottom of the chip (1301). Metal feedthroughs (1304) made from a metal selected from the group consisting of radium, platinum, titanium, iridium, palladium, gold, and stainless steel. The bottom cover (1306) is formed from one of the ceramics selected from the group consisting of aluminum oxide or zirconium oxide. The inner surface (1305), toward the solder ball, (1303) of the feed-through (1304) is plated with gold or with nickel. The ceramic cover (1306) is then attached to the box using a braze (1307) selected from the group consisting of: 50% titanium together with 50% nickel and gold. Electronics are then inserted and the metal top cover (of the same metal selected for the box) is laser welded in place.

Please amend the last paragraph on page 28 and continuing on page 29 to read as follows:

In one embodiment (Figure 16a), the internal-to-the-eye implanted part consists of two subsystems, the electrode component subretinally positioned and the electronic component epiretinally positioned. The electronics component, with its relatively high heat dissipation, is positioned at a distance, within the eye, from the electrode component placed near the retina that is sensitive to heat.

Please amend the second full paragraph on page 29 to read as follows:

An alternative embodiment of the invention has the electronic chip element implanted in the fatty tissue behind the eye and the electrode element placed subretinally or epiretinally, and power and signal communication between them by electromagnetic means including radio-frequency (RF), optical, and quasi-static magnetic fields, or by acoustic means including ultrasonic transducers.

Please amend the second full paragraph on page 30 to read as follows:

Another aspect includes a retinal prosthesis with (see Figure 1b) a physician's local external control unit (115) allowing the physician to exert setup control of parameters such as amplitudes, pulse widths, frequencies, and patterns of electrical stimulation. The physician's control unit (115) is also capable of monitoring information from the implanted unit (121) such as electrode current, electrode impedance, compliance voltage, and electrical recordings from the retina. The monitoring is done via the internal telemetry unit, electrode and electronics assembly (121).

Please amend the third full paragraph on page 32 to read as follows:

Corresponding to the Physician's Local Controller, but with much less capability, is the Patient's Controller. Figure 20 shows the patient's local controller unit. This unit can monitor and adjust brightness (2001), contrast (2002) and magnification (2003) of the image on a non-continuous basis. The magnification control (2003) adjusts magnification both by optical zoom lens control of the lens for the imaging means (Figure 1, 111), and by electronic adjustment of the image in the data processor (Figure 2, 113).

Please replace the abstract with:

Abstract

The present invention is an implantable electronic device formed within a biocompatible hermetic package. Preferably the implantable electronic device is used for a visual prosthesis for the restoration of sight in patients with lost or degraded visual function. The package may include a hard hermetic box, a thin film hermetic coating, or both.

In the Claims:

Please delete claims 1 – 268, without prejudice.

Please add claims 269- 309 as follows:

269. A visual prosthesis comprising:

an internal electronics unit, implanted within a living body, at least a portion of said internal electronics unit is formed within a biocompatible hermetic package; and

a plurality of electrodes driven by said internal electronics unit stimulating visual neurons to create a perception of a visual image.

270. The visual prosthesis according to claim 269, wherein said biocompatible hermetic package is a hermetic box.

271. The visual prosthesis according to claim 270, wherein said hermetic box includes a metal portion and a ceramic portion.

272. The visual prosthesis according to claim 271, wherein said metal portion is braised to said ceramic portion.

273. The visual prosthesis according to claim 269, further comprising a flip chip electrically connected to feed throughs in a ceramic portion.

274. The visual prosthesis according to claim 271, wherein said metal portion includes a metal ring braised to said ceramic portion and a metal lid welded to said metal ring.

275. The visual prosthesis according to claim 269, wherein said biocompatible hermetic package is a thin film.

276. The visual prosthesis according to claim 269, wherein said biocompatible hermetic package is partially a thin film and partially a hermetic box.

277. The visual prosthesis according to claim 275, wherein said thin film is a diamond coating.

278. The visual prosthesis according to claim 275, wherein said thin film is aluminum oxide.

279. The visual prosthesis according to claim 275, wherein said thin film is zirconium oxide.

280. The visual prosthesis according to claim 275, wherein said thin film is selected from the group consisting of titanium oxide, tantalum oxide and aluminum nitride.

281. The visual prosthesis according to claim 275, wherein said thin film is selected from the group consisting silicon oxide, silicon nitride, and silicon carbide.

282. The visual prosthesis according to claim 275, wherein said thin film is applied by ion-beam assisted deposition.

283. A visual prosthesis comprising:
a plurality of electrodes stimulating a retina; and
an internal electronics device controlling said plurality of electrodes and positioned within a vitreous humor, but distant from a retina.

284. The visual prosthesis according to claim 283, wherein said internal electronics device is positioned in the center of the vitreous humor.

285. The visual prosthesis according to claim 283, further comprising a thin film hermetic coating applied to said internal electronics device.

286. The visual prosthesis according to claim 285, wherein said thin film is a diamond like coating.

287. The visual prosthesis according to claim 285, wherein said thin film is aluminum oxide.

288. The visual prosthesis according to claim 285, wherein said thin film is zirconium oxide.

289. A visual prosthesis comprising:

an internal electronics unit, implanted within a living body in the vicinity of an eye, at least a portion of said internal electronics unit is formed within a biocompatible hermetic package; and

a plurality of electrodes driven by said internal electronics unit stimulating a retina to create a perception of a visual image.

290. The visual prosthesis according to claim 269, wherein said biocompatible hermetic package is a hermetic box.

291. The visual prosthesis according to claim 290, wherein said hermetic box includes a metal portion and a ceramic portion.

292. The visual prosthesis according to claim 291, wherein said metal portion is braised to said ceramic portion.

293. The visual prosthesis according to claim 289, further comprising a flip chip electrically connected to feed throughs in a ceramic portion.

294. The visual prosthesis according to claim 291, wherein said metal portion includes a metal ring braised to said ceramic portion and a metal lid welded to said metal ring.

295. The visual prosthesis according to claim 289, wherein said biocompatible hermetic package is a thin film.

296. The visual prosthesis according to claim 289, wherein said biocompatible hermetic package is partially a thin film and partially a hermetic box.

297. The visual prosthesis according to claim 295, wherein said thin film is a diamond coating.

298. The visual prosthesis according to claim 295, wherein said thin film is aluminum oxide.

299. The visual prosthesis according to claim 295, wherein said thin film is zirconium oxide.

300. The visual prosthesis according to claim 295, wherein said thin film is selected from the group consisting of titanium oxide, tantalum oxide and aluminum nitride.

301. The visual prosthesis according to claim 295, wherein said thin film is selected from the group consisting silicon oxide, silicon nitride, and silicon carbide.

302. The visual prosthesis according to claim 295, wherein said thin film is applied by ion-beam assisted deposition.

303. An implantable device comprising:
a ceramic substrate having feed throughs; and
active electronics supported by said ceramic substrate and electrically coupled to said feed throughs.

304. The implantable device according to claim 303, wherein said active electronics is an integrated circuit.

305. The implantable device according to claim 303, further comprising a hermetic package wherein said ceramic substrate forms part of said hermetic package.

306. The implantable device according to claim 303, wherein said implantable device is part of a visual prosthesis.

307. The implantable device according to claim 306, wherein said visual prosthesis is a retinal prosthesis.

308. The implantable device according to claim 303, wherein a side of said ceramic substrate opposite said active electronics is adapted to contact tissue.

309. An implantable device comprising:
a ceramic substrate having feed throughs;
a plurality of capacitors electrically coupled to said feed throughs and supported by said ceramic substrate; and
active electronics electrically coupled to said plurality of capacitors.

REMARKS

Claims 1 – 268 were pending in the parent application. The examiner divided those original claims into 17 inventions and required restriction to a single invention. Applicant elects group VIII in this divisional application. Claims 1 – 268 have been withdrawn without prejudice. New claims 269 – 309 have been added to respond to the restriction requirement and to more particularly point out applicant's invention. Applicant has redrafted the claims, but believes the new claims fall within the Examiner's group VIII, and represent a single invention.

In an effort to expedite prosecution of this application, Applicant has reviewed the above-identified application and is submitting this Preliminary Amendment which corrects typographical errors in the specification and the claims. No new matter is included. Additionally, typographical errors were encountered on Figures 1a, 1c, 1d, 6b, 6c, 10b, 10c, 10d, 10e, 11 (11a and 11b), 11b, 11d, 11e, and 17b. Redlined copies of the proposed corrections are included with this amendment. In order to simplify review of the application, Applicant is providing a full set of drawings (Figures 1a-20) that include the proposed amendments.

If for any reason the Examiner finds the application other than in condition for allowance, and the Examiner believe that a teleconference may be helpful, the Examiner is invited to call the undersigned attorney at (661) 775-3990 ext. 3129 to discuss the steps necessary for placing the application in condition for allowance.

Respectfully submitted,

10/12/01
Date

Scott B. Dunbar
Attorney for Applicant
Reg. No. 37,124

Second Sight, LLC
P.O. Box 905
Santa Clarita, CA 91380-9005
(661) 775-3990 x3129
(661) 775-1595 (fax)

Version with Markings to Show Changes Made

In the Specification:

Please amend the title on page 1 to read as follows:

Package for an Implantable Medical Device

Please add:

Cross Reference to Related Applications

This application is a division of US Application 09/515,383, filed February 29, 2000, entitled Retinal Color Prosthesis for Color Sight Restoration, which claims priority of US Provisional Application 60/125,873, filed March 24, 1999, entitled Method and Apparatus for Sight Restoration.

Please amend the first full paragraph on page 3 to read as follows:

Subsequently, Michelson (U.S. Patent No. 4,628,933), Chow (U.S. Patent Nos. 5,016,633; 5,397,350; 5,556,423), and De Juan (U.S. Patent No. 5,109,844) all were issued patents relating to a device for stimulating undamaged retinal cells. Chow and Michelson made use of photodiodes and electrodes. The photodiode was excited by incoming photons and produced a current at the electrode.

Please amend the third full paragraph on page 3 to read as follows:

Najafi, et al., (U.S. Patent No. 5,314,458), disclosed an implantable silicon-substrate based microstimulator with an external device which could send power and signal to the implanted unit by RF means. The incoming RF signal could be decoded and the incoming RF power could be rectified and used to run the electronics.

Please amend the fourth full paragraph on page 3 to read as follows:

Difficulties can arise if the photoreceptors, the electronics, and the electrodes all tend to be mounted at one place. One issue is the availability of sufficient area to ~~accomodate~~accommodate all of the devices, and another issue is the amount of power dissipation near the sensitive retinal cells. Since these devices are designed to be implanted into the eye, this potential overheating effect is a serious consideration.

Please amend the first full paragraph on page 4 to read as follows:

A desirable property of a retinal prosthetic system is making it possible for a physician to make adjustments on an on-going basis from outside the eye. One way of doing this would have a physician's control unit, which would enable the physician to make adjustments and monitor the eye condition. An additional advantageous feature would enable the physician to ~~preform~~ perform these functions ~~at a remote location~~ at a remote location, e.g., from his office. This would allow one physician to remotely monitor a number of patients remotely without the necessity of the patient coming to the office. A patient could be ~~travelling~~traveling distantly and obtain physician monitoring and control of the retinal color prosthetic parameters.

Please amend the last paragraph on page 4 and continuing on page 5 to read as follows:

By having a method and apparatus for the physician and the technician to initially set up and measure the internal activities and adjust these, the patient's needs can be better accommodated. The opportunity exists to measure internal activity and to allow the physician, using his ~~judgement~~judgment, to adjust settings and controls on the electrodes. Even the individual electrodes would be adjusted by way of the electronics controlling them. By having this done remotely, by remote means either by telephone or by the Internet or other such, it is clear that a physician would have the capability to intervene and make adjustment as necessary in a convenient and inexpensive fashion, to serve many patients.

Please amend the first through the fourth full paragraphs on page 12 to read as follows:

Figure 11c shows a variation of a form of the elongated electrode wherein the electrode is thinner and more recessed from the well sides;

Figure 11d shows a variation of a form of the elongated electrode~~,~~ wherein the electrode is squatter but recessed from the well sides;

Figure 11e shows a variation of a form of the elongated electrode~~,~~ wherein the electrode is a mushroom shape with the sides of its tower recessed from the well sides and its mushroom top above the oxide insulating material;

Figure 12a shows the coil attachment to two different conducting pads at an electrode nodes~~;~~

Please amend the eleventh through the twelfth full paragraphs on page 13 to read as follows:

Figure 19 shows the physician's remote controller that has the same functionality inside as the physician's controller but with the addition of communication means such as telemetry or telephone modem; and

Figure 20 shows the patient's controller unit~~;~~.

Please amend the first full paragraph on page 14 to read as follows:

Functionally, there are three main parts to an embodiment of this retinal color prosthesis invention. See Figure 1a. Figure 1a is oriented toward showing the main structural parts and subsystems, with a dotted enclosure to indicate~~ion~~ a functional intercommunications aspect. The first part of the embodiment is external (1) to the eye. The second part is implanted internal (2) to the eye. The third part is means for communication between those two parts (3). Structurally there are two parts. One part is external (1) to the eye and the other part (2) is implanted within the eye. Each of these structural parts contains two way communication circuitry for communication (3) between the internal (2) and external (1) parts.

Please amend the last paragraph on page 14 and continuing on page 15 to read as follows:

Examining further the embodiment of the subsystems of the external part, see Figure 1b. These include an external color imager (111), an eye-motion compensation system (112), a head-motion compensation system (131), a processing unit (113), a patient's controller (114), a physician's local controller (115), a physicians hand-held palm-size pocket-size unit (1301~~6~~), a physician's remote controller (117), and a telemetry means (118). The color imager is a color video camera such as a CCD or CMOS video camera. It gathers an image approximating what the eyes would be seeing if they were functional.

Please amend the last paragraph on page 15 and continuing on page 16 to read as follows:

Color information (See Figure 2a), in the first preferred embodiment, is encoded by time sequences of pulses (201) separated by varying amounts of time (202), and also with the pulse duration being varied in time (203). The basis for the color encoding is the individual color code reference (211 through 217~~8~~). The electrodes stimulate the target cells so as to create a color image for the patient, corresponding to the original image as seen by the video camera, or other imaging means. Using temporal coding of electrical stimuli placed (cf. Figure 2b, 220, Figure 2c, 230) on or near the retina (Figure 2b and Figure 2c, 221, 222) the perception of color can be created in patients blinded by outer retinal degeneration. By sending different temporal coding schemes to different electrodes, an image composed of more than one color can be produced. Figure 2 shows one stimulation protocol. Cathodic stimuli (202) are below the zero plane (220) and anodic stimuli (203) are above. All the stimulus rates are either "fast" (203) or "slow" (202) except for green (214), which includes an intermediate stimulus rate (204). The temporal codes for the other colors are shown as Red (211), as Magenta (212), as Cyan (213), as Yellow (215), as Blue (216), as Neutral (217~~8~~). This preferred embodiment is directed toward electrodes which are less densely packed in proximity to the retinal cells.

Please amend the first full paragraph on page 16 to read as follows:

Color information, in a second preferred embodiment, is sent from the video data processing unit to the electrode array, where each electrode has been determined by test to stimulate one of a bipolar type: red-center green-surround, green-center-red-surround, blue-center-yellow-surround, or yellow-center-blue-surround. In this embodiment, electrodes which are small enough to interact with a single cell, or at most, a few cells~~. These electrodes~~ are placed in the vicinity of individual bipolar cells, which react to a stimulus with nerve pulse rates and nerve pulse structure (i.e., pulse duration and pulse amplitude). Some of the bipolar cells, when electrically, or otherwise, stimulated, will send red-green signals to the brain. Others will send yellow-blue signals. This refers to the operation of the normal retina. In the normal retina, red or green color photoreceptors (cone cells) send nerve pulses to the red-green bipolar cell which then pass some form of this information up to the ganglion cells and then up to the visual cortex of the brain. With small electrodes individual bipolar cells can be excited in a spatial, or planar, pattern. Small electrodes are those with tip from 0.1 μm to 15 μm, and which individual electrodes are spaced apart from a range 8 μm to 24 μm, so as to approximate a one-to-one correspondence with the bipolar cells. The second preferred embodiment is oriented toward a more densely packed set of electrodes.

Please amend first full paragraph on page 17 to read as follows:

Regardless of a particular theory of color vision, the impinging of colored light on the normal cones, and possibly rods, give rise in some fashion to the perception of color, i.e., multi-spectral vision. In the time-pulse coding color method, above, the absence of all, or sufficient, numbers of working cones (and rods) suggests a generalization of the particular time-pulse color encoding method. The generalization is based on the known, or partly known, neuron conduction pathways in the retina. The cone cells, for example, signal to bipolar cells, which in turn signal the ganglion cells. The original spatial-temporal-color (including black, white) schem~~e~~a for conveying color information as the cone is struck by particular wavelength photons is then transformed to a patterned signal firing of the next cellular level, say the bipolar cells, unless the cones are absent or don't function. Thus, this second level of patterned signal firing is what one wishes to supply to induce the perception of color vision.

Please amend the second full paragraph on page 17 to read as follows:

The secondary layer of patterned firing may be close to the necessary primary pattern, in which case the secondary pattern (**S**) may be represented as $\mathbf{P} * (\mathbf{1} + \in)$. The * indicates matrix multiplication. **P** is the primary pattern, represented as a matrix

$$\mathbf{P} = \begin{bmatrix} p_{11} & p_{1j} \\ p_{k1} & p_{kj} \end{bmatrix}$$

where **P** represents the light signals of a particular spatial-temporal pattern, e.g., flicker signals for green. The output from the first cell layer, say the cones, is then **S**, the secondary pattern. This represents the output from the bipolar layer in response to the input from the first (cone) layer. If $\mathbf{S} = \mathbf{P} * (\mathbf{1} + \in)$, where ~~(~~**1** represents a ~~(~~vector~~)~~ and $\in$ represents a small deviation applied to the vector **1**, then **S** is represented by **P** to the lowest order, and by $\mathbf{P} * (\mathbf{1} + \in)$ to the next order. Thus, the response may be seen as a zero order effect and a first order linear effect. Additional terms in the functional relationship are included to completely define the functional relationship. If **S** is some non-linear function of **P**, finding **S** by starting with **P** requires more terms then the linear case to define the bulk of the functional relationship. However, regardless of the details of one color vision theory or another, on physiological grounds **S** is some function of **P**. As in the case of fitting individual patients with lenses for their glasses, variations of parameters are expected in fitting each patient to a particular temporal coding of electrical stimuli.

Please amend the first full paragraph on page 18 to read as follows:

As cited above, Greenberg (1998) indicates that electrical and photonic stimulation of the normal retina operate via similar mechanisms. Thus, even though electrical stimulation of a retina damaged by outer retinal degeneration is different from the electrical stimulation of a normal retina, the temporal relationships are expected to be analogous.

Please amend the second full paragraph on page 18 to read as follows:

To explain this, it is noted that electrical stimulation of the normal retinal is accomplished by stimulating the photoreceptor cells (including the color cells activated differentially according to the color of light impinging on them). For the outer retinal degeneration, it is precisely these photoreceptor cells which are missing. Therefore, the electrical stimulation in this case proceeds by way of the cells next up the ladder toward the optic nerve, namely, the bipolar cells.

Please amend the fourth full paragraph on page 18 to read as follows:

In Figure 2, which is extrapolated from external-to-the-eye electrical stimulation data of Young (1977) and from light stimulation data of Festinger, Allyn, and White (1971), there is shown data that would be applicable to the photoreceptor cells. One may scale the data down based on the ratio of the photoreceptor time constant (about 20 milliseconds) to that of the bipolar cells (about 9 milliseconds). Consequently, 50 milliseconds on the time scale in Figure 2 now corresponds to 25 milliseconds. Advantageously, stimulation rates and duration of pulses, as well as pulse widths may be chosen which apply to the electrode stimulation of the bipolar cells of the retina.

Please amend the first full paragraph on page 19 to read as follows:

In one aspect of an embodiment (Figure 1b), light amplitude is recorded by the external imager (111) . The video data processing unit usesing a logarithmic encoding scheme (113) to convert the incoming light amplitudes into the logarithmic electrical signals of these amplitudes (113). These electrical signals are then passed on by telemetry (118), (121), to the internal implant (121) which results in the retinal cells (120) being stimulated via the implanted electrodes (121), in this embodiment as part of the internal implant (121). Encoding is done outside the eye, but may be done internal to the eye, with a sufficient internal computational capability.

Please amend the last paragraph on page 19 and continuing on page 20 to read as follows:

The retinal prosthesis system contains a color imager (Figure 1b, 111) such as a color CCD or CMOS video camera. The imaging output data is typically processed (113) into a pixel-based format compatible with the resolution of the implanted system. This processed data (113) is then associated with corresponding electrodes and amplitude and pulse-width and frequency information is sent by telemetry (118) into the internal unit coils, (311), (313), (314) (see Figure 3a). Electromagnetic energy, is transferred into and out from an electronic component (311) located internally in the eye (312), using two insulated coils, both located under the conjunctiva of the eye with one free end of one coil (313) joined to one free end of the second coil (314), the second free end of said one coil joined to the second free end of said second coil. The second coil (314) is located in proximity to a coil (311) which is a part of said internally located electronic component, or, directly to said internally located electronic component (311). The larger coil is positioned near the lens of the eye. The larger coil is fastened in place in its position near the lens of the eye, for example, by suturing. Figure 3b represents an embodiment of the telemetry unit temporally located near the eye, including an external temporal coil (321), an internal (to the eye) coil (31~~42~~), an external-to-the-eye electronic chip (320), dual coil transfer units (314, 323), (321, 322) and an internal-to-the-eye electrode array (325). The advantage of locating the external electronics in the fatty tissue behind the eye is that there is a reasonable amount of space there for the electronics and in that position it appears not to interfere with the motion of the eye.

Please amend the second full paragraph on page 20 to read as follows:

For the light modulation (Figure 3d) case, a light emitting diode (LED) or laser diode or other light generator (361), capable of being modulated, acts as the information transmitter. Information is transferred serially by modulating the light beam, and energy is extracted from the light signal after it is converted to electricity. A photo-detector (362), such as a photodiode, which turns the modulated light signal into a modulated electrical signal, is used as a receiver. A set of a photo-generator and a photo-detector are on the implant (121) and a set is also external to the eye.

Please amend first full paragraph on page 21 to read as follows:

The internal-to-the eye implanted part shows a coil (551), which connects, to both a rectifier circuit (552) and to a demodulator circuit (553). The demodulator connects to a switch control unit (554). The rectifier (552) connects to a plurality of diodes (555) which rectify the current to direct current for the electrodes (556); the switch control sets the electrodes as on or off as they set the switches (557). The coils (408) and (551) serve to connect inductively the internal-to-the-eye (4500) subsystem and the external-to-the patient (5400) subsystem by electromagnetic waves. Both power and information can be sent into the internal unit. Information can be sent out to the external unit. Power is extracted from the incoming electromagnetic signal and may be accumulated by capacitors connected to each electrode or by capacitive electrodes themselves.

Please amend first full paragraph on page 23 to read as follows:

Figure 10c shows an embodiment with the iridium slug as in Figure 10b, however, the top of the iridium slug (1011) is recessed below the level of the insulator; Figure 10d indicates an embodiment with the iridium slug (1011) coming to a point and insulation along its sides (1021), as well as a being within the overall insulation structure (1021). Figure 10e indicates an embodiment of a method for fabricating the iridium electrodes. On a substrate (1013) of silicon, an aluminum pad (1022) is deposited. On the pad, the conductive adhesive (1023) is laid and platinum or iridium foil (1024) is attached thereby. A titanium ring (1025) is placed, sputtered, plated, ion implanted, ion beam assisted deposited (IBAD) or otherwise attached to the platinum or iridium foil (1024). Silicon carbide, diamond-like coating, silicon nitride and silicon oxide in combination, titanium oxide, tantalum oxide, aluminum nitride, aluminum oxide or zirconium oxide (1012) or other insulator can adhere better to the titanium (1025) while it would not otherwise adhere as well to the platinum or iridium foil (1024). The depth of the well for the iridium electrodes ranges from 0.1 μm to 1 mm.

Please amend the last paragraph on page 23 and continuing on page 24 to read as follows:

Another aspect of an embodiment of the invention is the elongated electrode, which are designed to stimulate deeper retinal cells, in one embodiment, by penetrating the retina. By getting closer to the target cells for stimulation, the current required for stimulation is lower and the focus of the stimulation is more localized. The lengths chosen are 100 microns~~(m~~ through 500 ~~(m~~microns, including 300 ~~(m~~microns. Figure 8c is a rendering of an elongated epiretinal electrode array with the electrodes shown as pointed electrical conductors (820), embedded in an electrical insulator (818), where the elongated electrodes (~~811~~817) contact the retina in a conformal manner, however, penetrating into the retina (814).

Please amend the first full paragraph of page 24 to read as follows:

These elongated electrodes, in an aspect of this of an embodiment of the invention may be of all the same length. In a different aspect of an embodiment, they may be of different lengths. Said electrodes may be of varying lengths (Figure 8, 8172~~0~~), such that the overall shape of said electrode group conforms to the curvature of the retina (814). In either of these cases, each may penetrate the retina from an epiretinal position (Figure 8a, 811), or, in a different aspect of an embodiment of this invention, each may penetrate the retina from a subretinal position (Figure 9b, 817).

Please amend the last paragraph on page 24 and continuing on page 25 to read as follows:

Figure 11 (a-e) demonstrates a preferred structure of, and method of, making, spiked and mushroom platinum electrodes. Examining Figure 11a, one sees that the support for the flat electrode (1103) and other components such as electronic circuits (not shown) ~~is~~on the silicon substrate (1101). An aluminum pad (1102) is placed where an electrode or other component is to be placed ~~(1102)~~. In order to hermetically seal-off the aluminum and silicon from any contact with biological activity, a metal foil (1103), such as platinum or iridium, is applied to the aluminum pad (1102) using conductive adhesive (1104). Electroplating is not used since a layer formed by electroplating, in the range of the required thinness, has small-scale defects or holes which destroy the hermetic character of the layer. A titanium ring (1105) is next placed on the platinum or iridium foil (1103). Normally, this placement is by ion implantation, sputtering or ion beam assisted deposition (IBAD) methods. Silicon carbide, diamond-like coating, silicon nitride and silicon oxide in combination, titanium oxide, tantalum oxide, aluminum nitride, aluminum oxide or zirconium oxide (1106) is placed on the silicon substrate (1101) and the titanium ring (1105). In one embodiment, an aluminum layer (1107) is plated onto exposed parts of the titanium ring (1105) and onto the silicon carbide, diamond-like coating, silicon nitride and silicon oxide in combination, titanium oxide, tantalum oxide, aluminum nitride, aluminum oxide or zirconium oxide (1106). In this embodiment, the aluminum (1107) layer acts as an electrical conductor. A mask (1108) is placed over the aluminum layer (1107).

Please amend the first full paragraph on page 25 to read as follows:

In forming an elongated, non-flat, electrode ~~platinum~~ (Figure 11b), platinum is electroplated onto the platinum or iridium foil (1103). Subsequently, the mask (1108) is removed and insulation (1110) is applied over the platinum electrode (1109).

Please amend the second full paragraph on page 25 to read as follows:

In Figure 11c, a platinum electrode (1109) is shown which is more internal to the well formed by the silicon carbide, diamond-like coating, silicon nitride and silicon oxide in combination, titanium oxide, tantalum oxide, aluminum nitride, aluminum oxide or zirconium oxide and its titanium ring. The electrode (1109) is also thinner and more elongated and more pointed. Figure 11d shows a platinum electrode formed by the same method as was used in Figures 11a, 11b, and 11c. The platinum electrode (1192) is more internal to the well formed by the silicon carbide, diamond-like coating, silicon nitride and silicon oxide in combination, titanium oxide, tantalum oxide, aluminum nitride, aluminum oxide or zirconium oxide and its titanium ring as was the electrode (1109) in Figure 11c. However it is less elongated and less pointed.

Please amend the third full paragraph on page 25 to read as follows:

The platinum electrode is internal to the well formed by the silicon carbide, diamond-like coating, silicon nitride and silicon oxide in combination, titanium oxide, tantalum oxide, aluminum nitride, aluminum oxide or zirconium oxide and its titanium ring; said electrode whole angle at it's peak being in the range from 1° to 120°; the base of said conical or pyramidal electrode ranging from 1 ~~μ~~micron to 500 ~~μ~~micron; the linear section of the well unoccupied by said conical or pyramidal electrode ranging from zero to one-third.

Please amend the first full paragraph on page 26 to read as follows:

Information transmitted electromagnetically into or out of the implanted retinal color prosthesis utilizes insulated conducting coils so as to allow for inductive energy and signal coupling. Figure 12b shows an insulated conducting coil and insulated conducting electrical pathways, e.g., wires, attached to substrates at what would otherwise be electrode nodes, with flat, recessed metallic, conductive electrodes (1201). In referring to wire or wires, insulated conducting electrical pathways are included, such as in a "two-dimensional" "on-chip" coil or a "two-dimensional" coil on a ~~poly~~polyimide substrate, and the leads to and from these "two-dimensional" coil structures. A silicon carbide, diamond-like coating, silicon nitride and silicon oxide in combination, titanium oxide, tantalum oxide, aluminum nitride, aluminum oxide or zirconium oxide (1204) is shown acting as both an insulator and an hermetic seal. Another aspect of the embodiment is shown in Figure 12d~~a~~. The electrode array unit (1201) and the electronic circuitry unit (1202) can be on one substrate, or they may be on separate substrates (1202) joined by an insulated wire or by a plurality of insulated wires (1203). Said separate substrate units can be relatively near one another. For example, they might lie against a retinal surface, either epiretinally or subretinally placed. Two substrates units connected by insulated wires may carry more electrodes than if only one substrate with electrodes was employed, or it might be arranged with one substrate carrying the electrodes, the other the electronic circuitry. Another arrangement has the electrode substrate or substrates placed in a position to stimulate the retinal cells, while the electronics are located closer to the lens of the eye to avoid heating the sensitive retinal tissue.

Please amend the second full paragraph of page 26 to read as follows:

In all of the Figures 12a, 12b, and 12c, a coil (1205) is shown attached by an insulated wire. The coil can be a coil of wire, or it can be a "two dimensional" trace as an "on-chip" component or as a component on polyimide. This coil can provide a stronger electromagnetic coupling to an outside-the-eye source of power and of signals. Figure 12c~~d~~ shows an externally placed aluminum (conductive) trace instead of the electrically conducting wire of Figure 12d~~e~~. Also shown is an electrically insulating adhesive (1208) which prevents electrical contact between the substrates (1202) carrying active circuitry (1209).

Please amend the first full paragraph of page 27 to read as follows:

All structures, which are subject to corrosive action as a result of being implanted in the eye, or, those structures which are not completely biocompatible and not completely safe to the internal cells and fluids of the eye require hermetic sealing. Hermetic sealing may be accomplished by coating the object to be sealed with silicon carbide, diamond-like coating, silicon nitride and silicon oxide in combination, titanium oxide, tantalum oxide, aluminum nitride, aluminum oxide or zirconium oxide. These materials also provide electrical insulation. The method and apparatus of hermetic sealing by aluminum and zirconium oxide coating is described in ~~a pending~~ U. S. Patent Application, Serial Number 08/994,515, now U.S. Patent No. 6,043,437. The methods of coating a substrate material with the hermetic sealant include sputtering, ion implantation, and ion-beam assisted deposition (IBAD).

Please amend the second full paragraph on page 27 to read as follows:

Another aspect of an embodiment of the invention is hermetically sealing the silicon chip (1301) by placing it in a metal or ceramic box (1302) of rectangular cross-section with the top and bottom sides initially open (Figure 13). The box may be of one (1302) of the metals selected from the group comprising platinum, iridium, palladium, gold, and stainless steel. Solder balls (1303) are placed on the "flip-chip", i.e., a silicon-based chip that has the contacts on the bottom of the chip (1301). Metal feedthroughs (1304) made from a metal selected from the group consisting of radium, platinum, titanium, iridium, palladium, gold, and stainless steel. The bottom cover (1306) is formed from one of the ceramics selected from the group consisting of aluminum oxide or zirconium oxide. The inner surface (13~~8~~05), toward the solder ball, (13~~8~~03)~~)~~ of the feed-through (13~~8~~04) is plated with gold or with nickel. The ceramic cover (13~~8~~06) is then attached to the box using a braze (13~~8~~07) selected from the group consisting of: 50% titanium together with 50% nickel and gold. Electronics are then inserted and the metal top cover (of the same metal selected for the box) is laser welded in place.

Please amend the last paragraph on page 28 and continuing on page 29 to read as follows:

In one embodiment (Figure 16a), the internal-to-the-eye implanted part consists of two subsystems, the electrode component subretinally positioned and the electronic component epiretinally positioned. The electronics component, with its relatively high heat dissipation, is positioned at a distance, within the eye, from the electrode component placed near the retina that is sensitive to heat.

Please amend the second full paragraph on page 29 to read as follows:

An alternative embodiment of the invention has the electronic chip element implanted in the fatty tissue behind the eye and the electrode element placed subretinally or epiretinally, and power and signal communication between them by electromagnetic means including radio-frequency (~~rf~~RF), optical, and quasi-static magnetic fields, or by acoustic means including ultrasonic transducers.

Please amend the second full paragraph on page 30 to read as follows:

Another aspect includes a retinal prosthesis with (see Figure 1b~~a~~) a physician's local external control unit (115) allowing the physician to exert setup control of parameters such as amplitudes, pulse widths, frequencies, and patterns of electrical stimulation. The physician's control unit (115) is also capable of monitoring information from the implanted unit (121) such as electrode current, electrode impedance, compliance voltage, and electrical recordings from the retina. The monitoring is done via the internal telemetry unit, electrode and electronics assembly (121).

Please amend the third full paragraph on page 32 to read as follows:

Corresponding to the Physician's Local Controller, but with much less capability, is the Patient's Controller. Figure 20 shows the patient's local controller unit. This unit can monitor and adjust brightness (2001), contrast (2002) and magnification (2003) of the image on a non-continuous basis. The magnification control (2003) adjusts magnification both by optical zoom lens control of the lens for the imaging means (Figure 1, 111), and by electronic adjustment of the image in the data processor (Figure 2, 113).

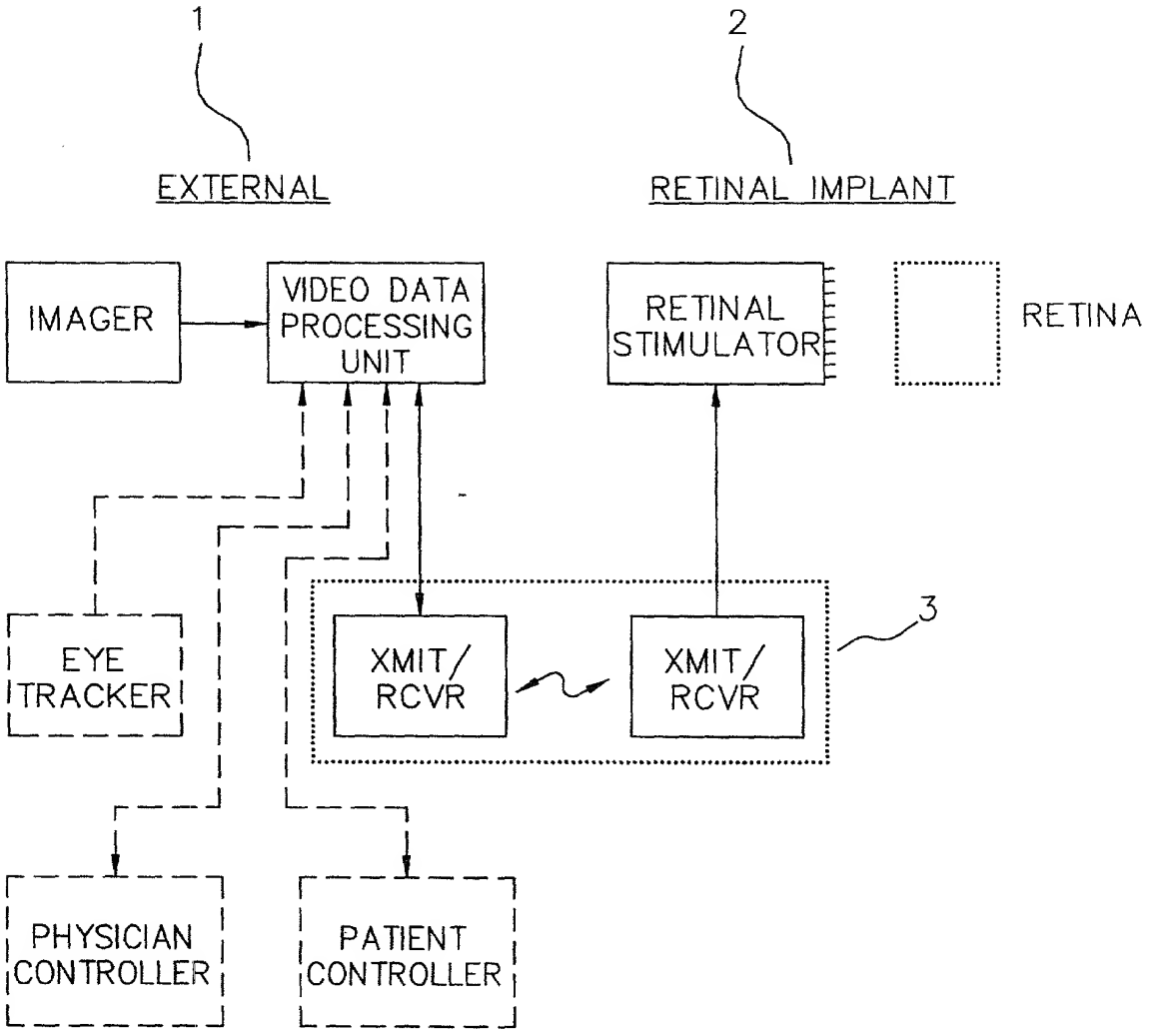

1
2
EXTERNAL
RETINAL IMPLANT
IMAGER
VIDEO DATA PROCESSING UNIT
RETINAL STIMULATOR
RETINA
EYE TRACKER
XMIT/ RCVR
XMIT/ RCVR
3
PHYSICIAN CONTROLLER
PATIENT CONTROLLER

Fig. 1a

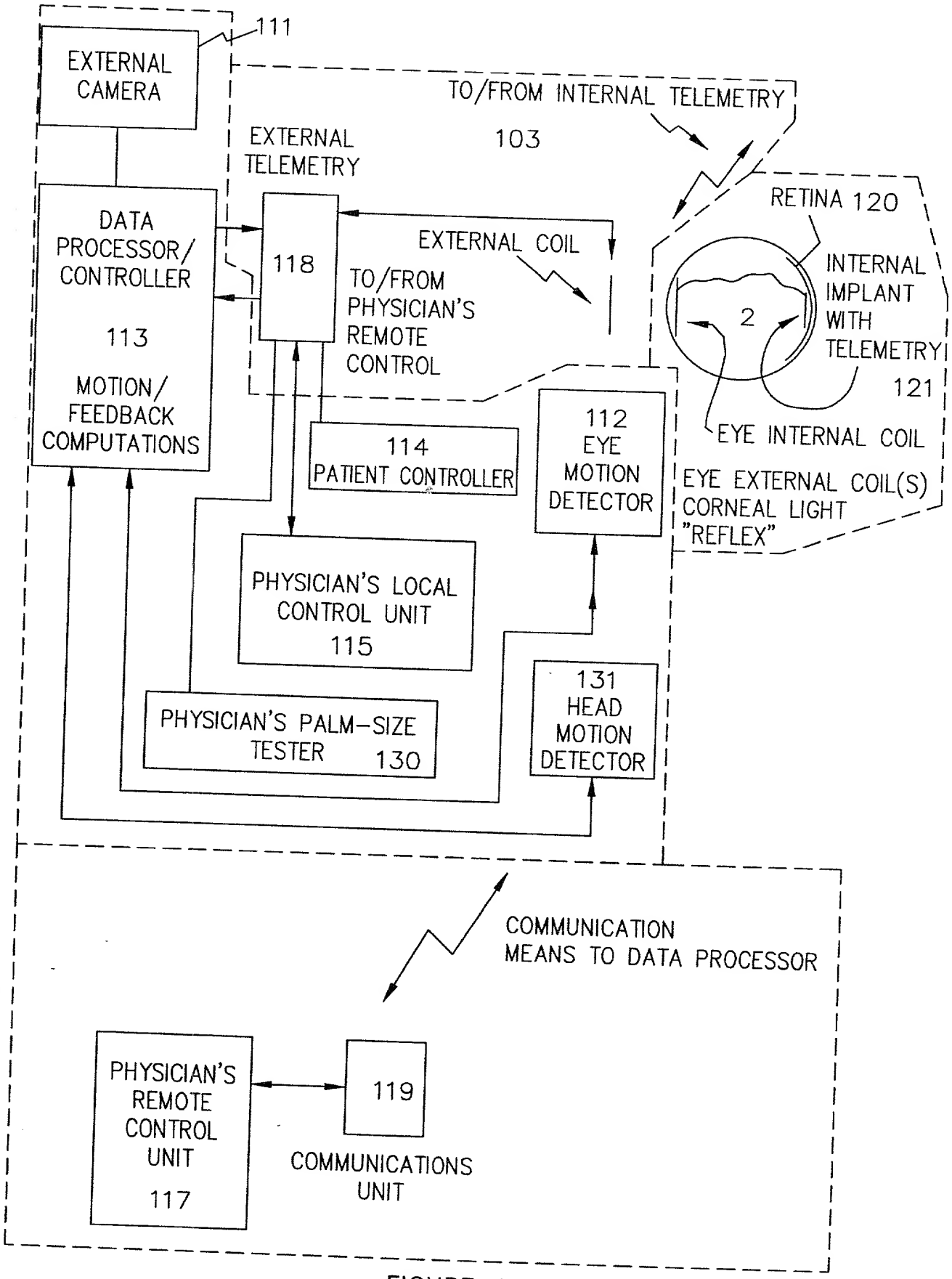

111
EXTERNAL CAMERA
TO/FROM INTERNAL TELEMETRY
103
EXTERNAL TELEMETRY
RETINA 120
DATA PROCESSOR/ CONTROLLER
113
MOTION/ FEEDBACK COMPUTATIONS
118
EXTERNAL COIL
TO/FROM PHYSICIAN'S REMOTE CONTROL
INTERNAL IMPLANT WITH TELEMETRY
2
121
EYE INTERNAL COIL
EYE EXTERNAL COIL(S)
CORNEAL LIGHT "REFLEX"
114
PATIENT CONTROLLER
112
EYE MOTION DETECTOR
PHYSICIAN'S LOCAL CONTROL UNIT
115
131
HEAD MOTION DETECTOR
PHYSICIAN'S PALM-SIZE TESTER
130
COMMUNICATION MEANS TO DATA PROCESSOR
PHYSICIAN'S REMOTE CONTROL UNIT
117
119
COMMUNICATIONS UNIT

FIGURE 1b

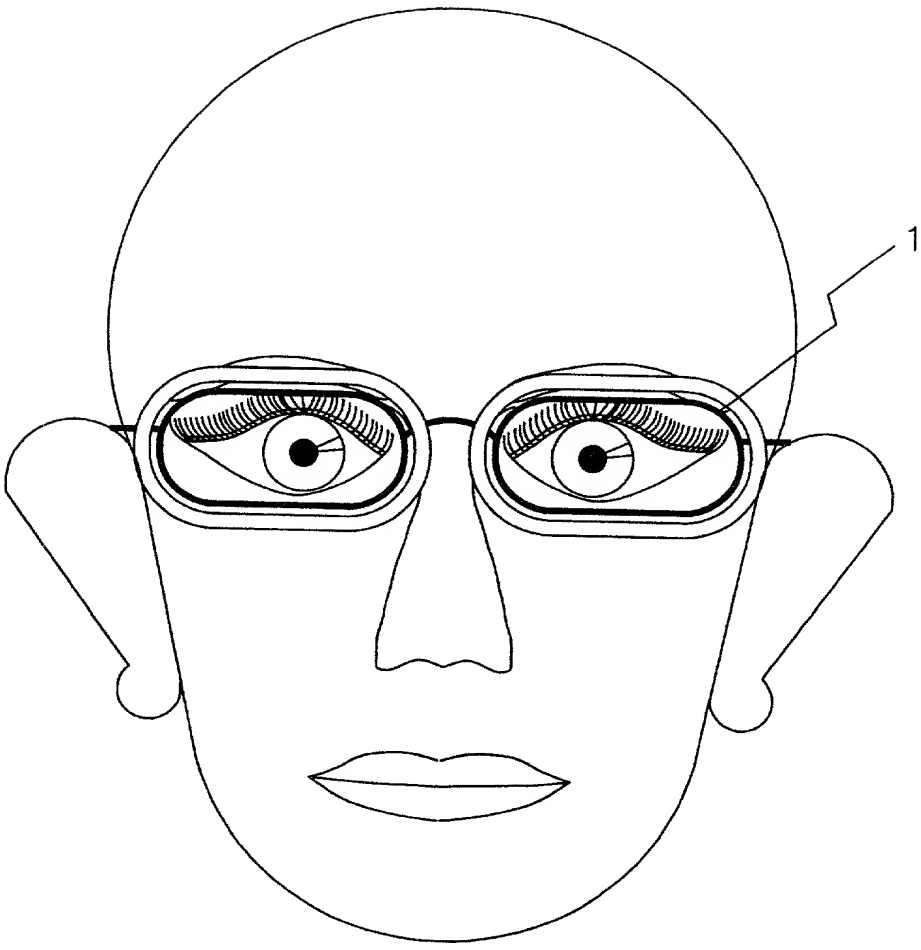


Fig. 1c

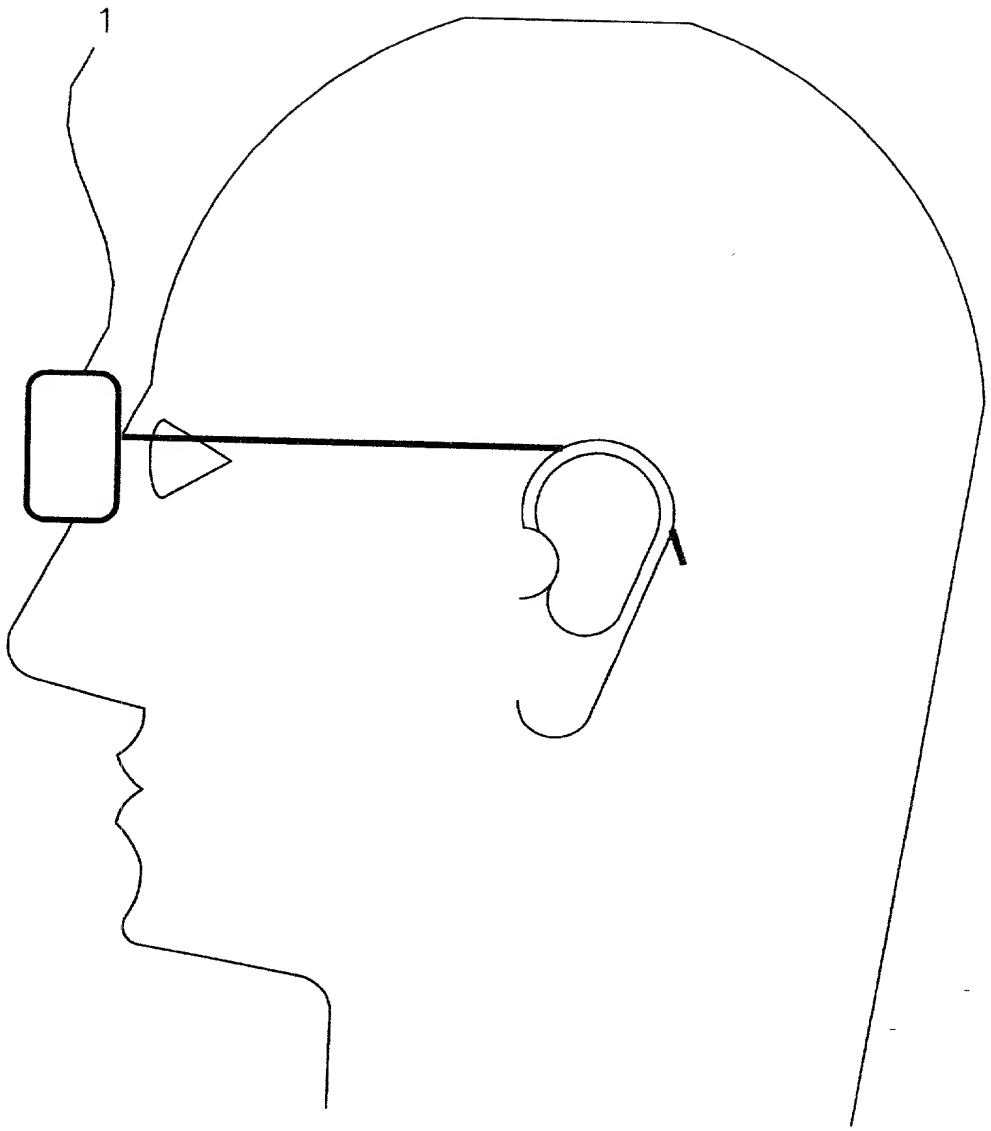


Fig 1d

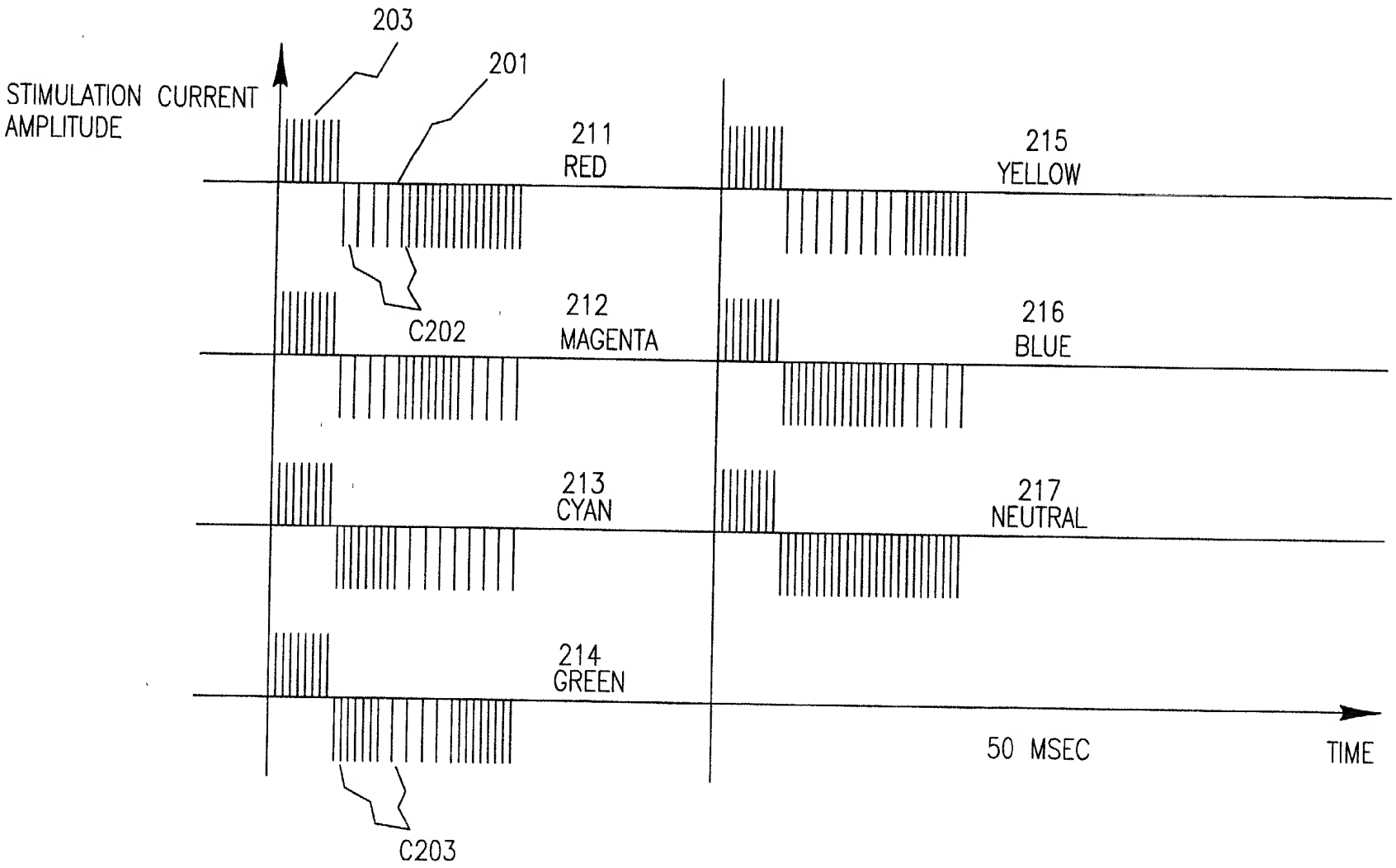


FIGURE 2a
COLOR CODING

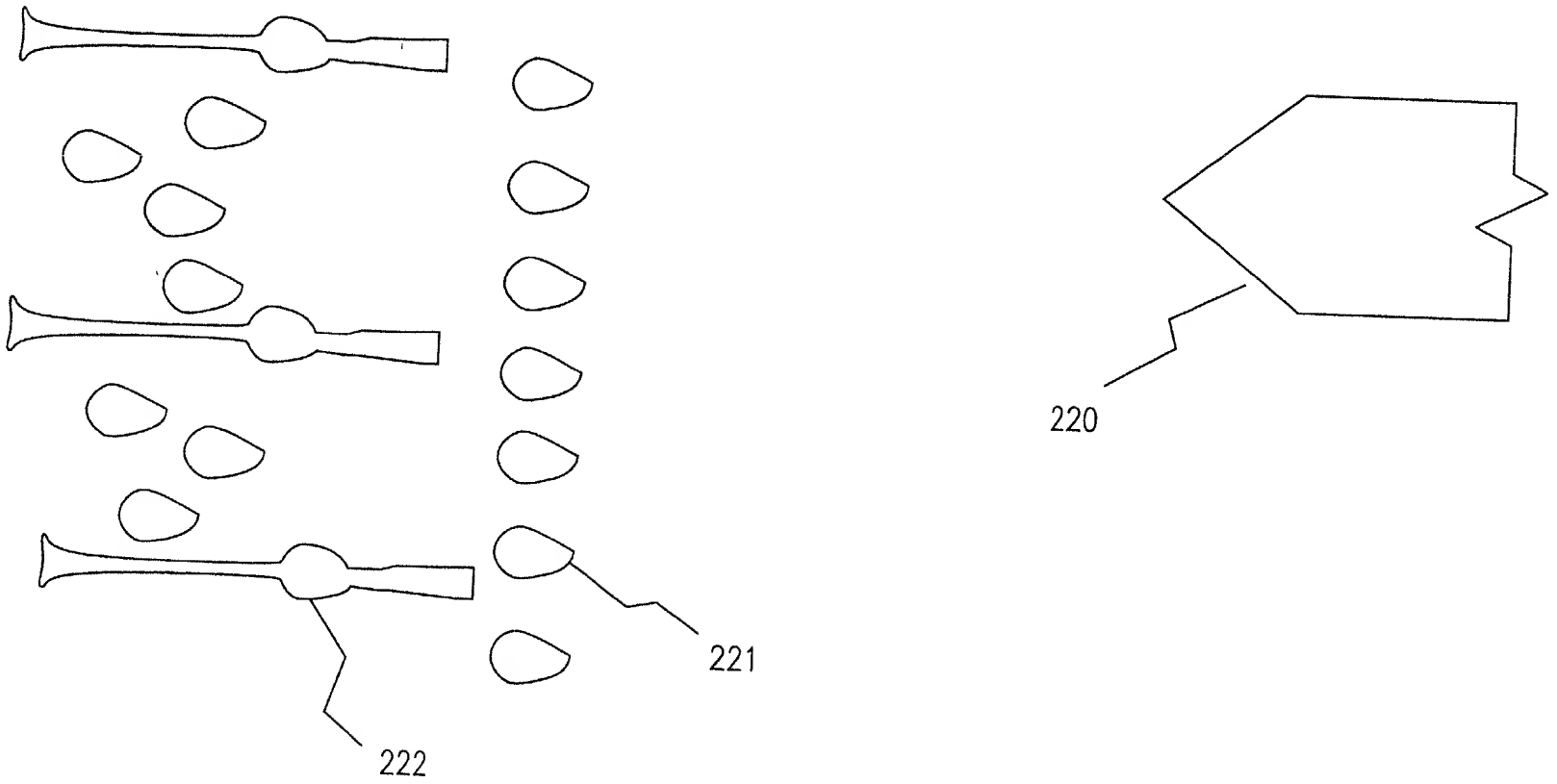


FIGURE 2b

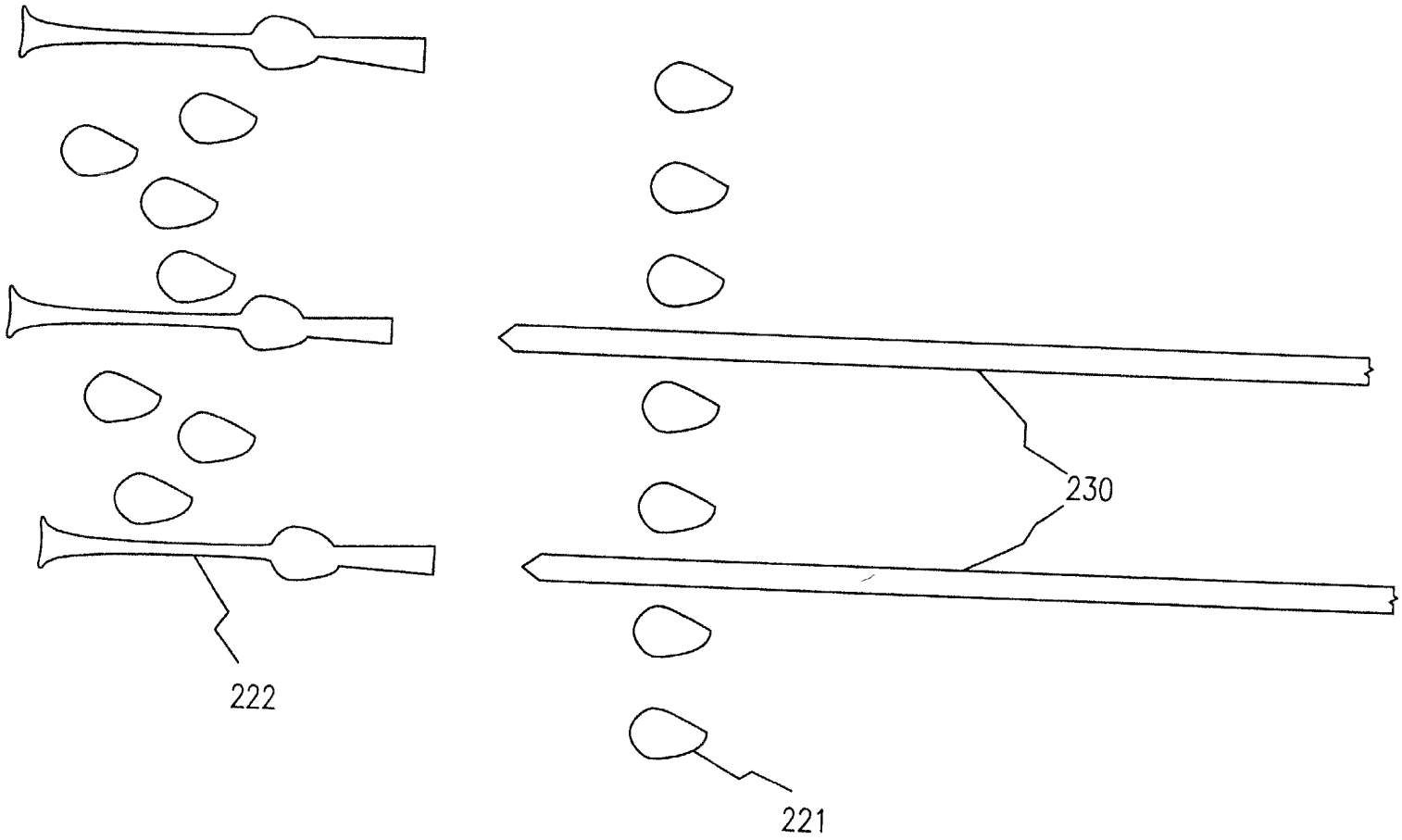
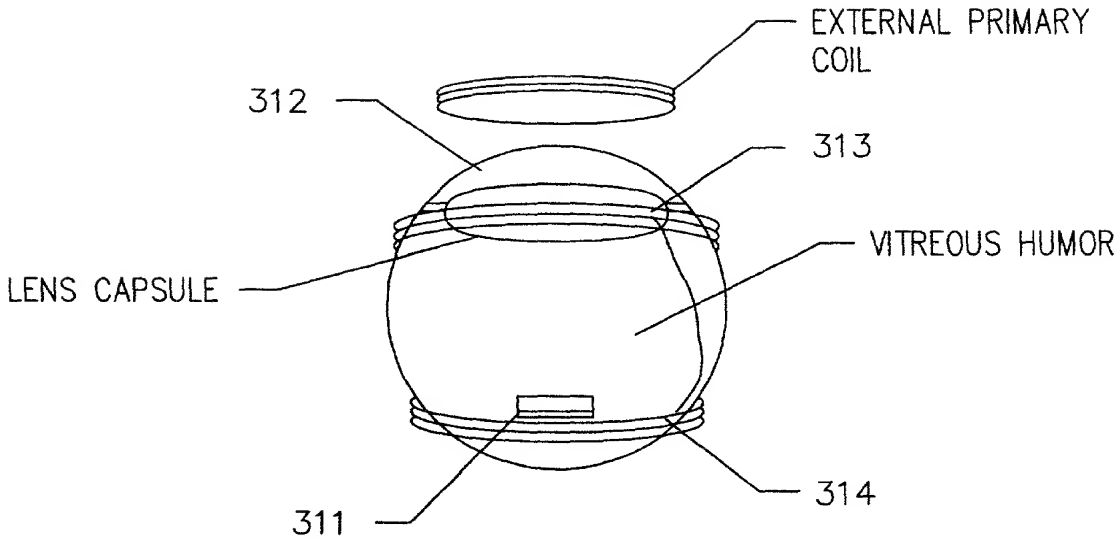


FIGURE 2c



EXTERNAL/INTERNAL TELEMETRY UNIT –
EXTERNAL COIL/INTERNAL COIL /INTERNAL CHIP

FIGURE 3a

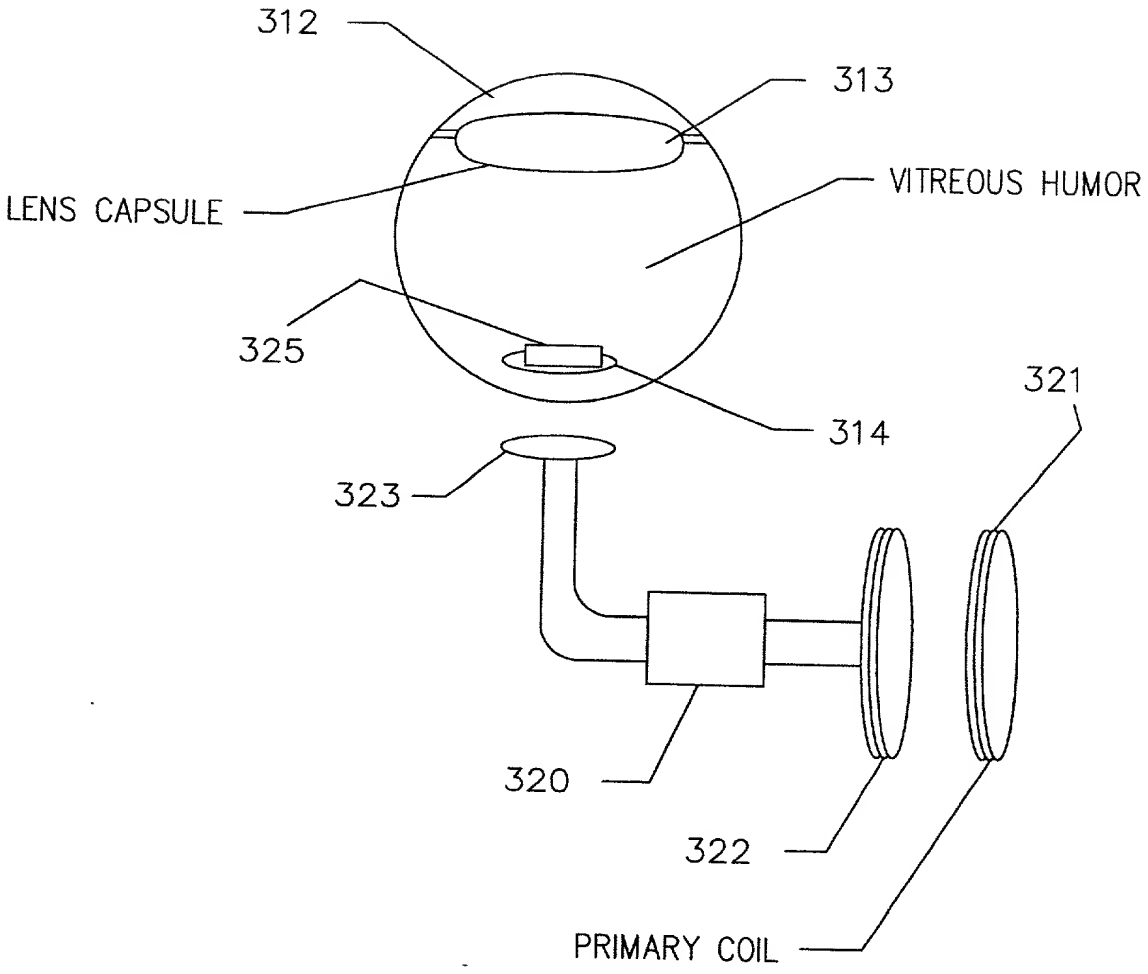

312
313
LENS CAPSULE
VITREOUS HUMOR
325
314
321
323
320
322
PRIMARY COIL

FIGURE 3b

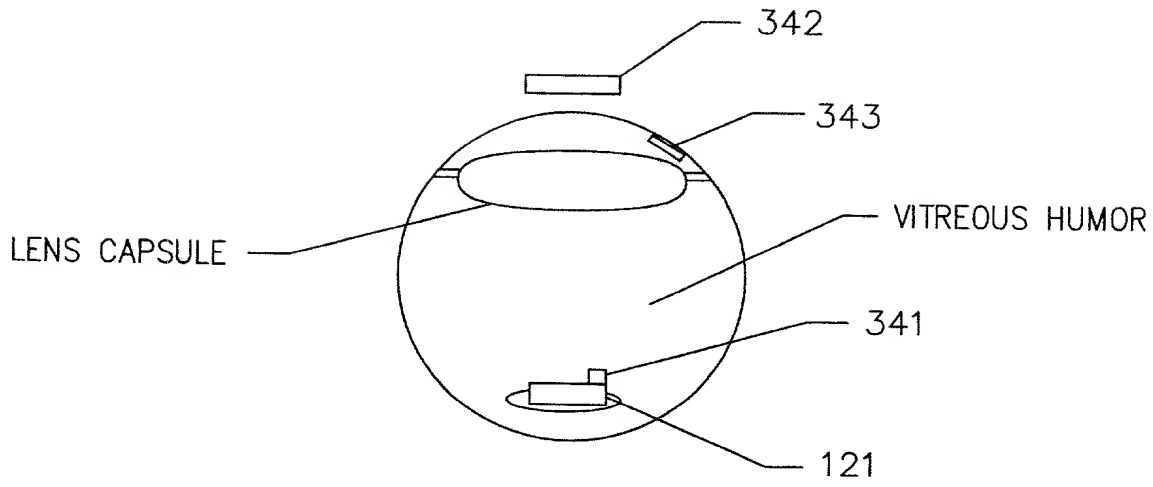


FIGURE 3c

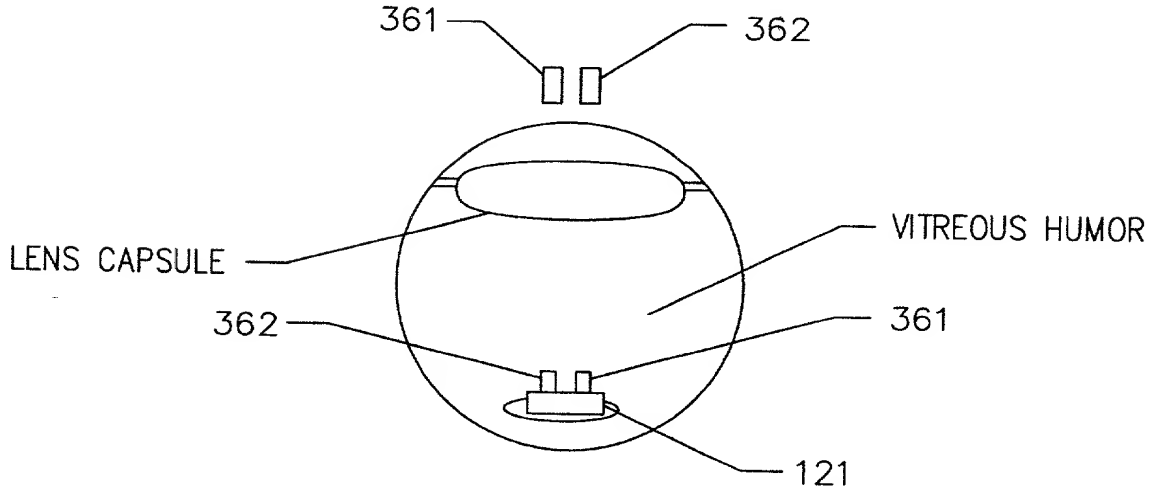


FIGURE 3d

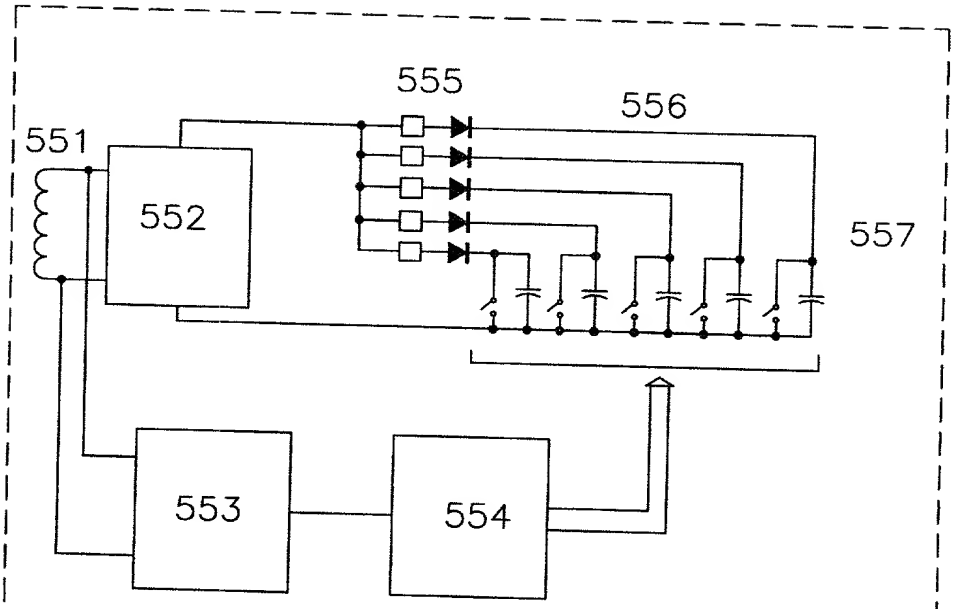


FIGURE 5

500

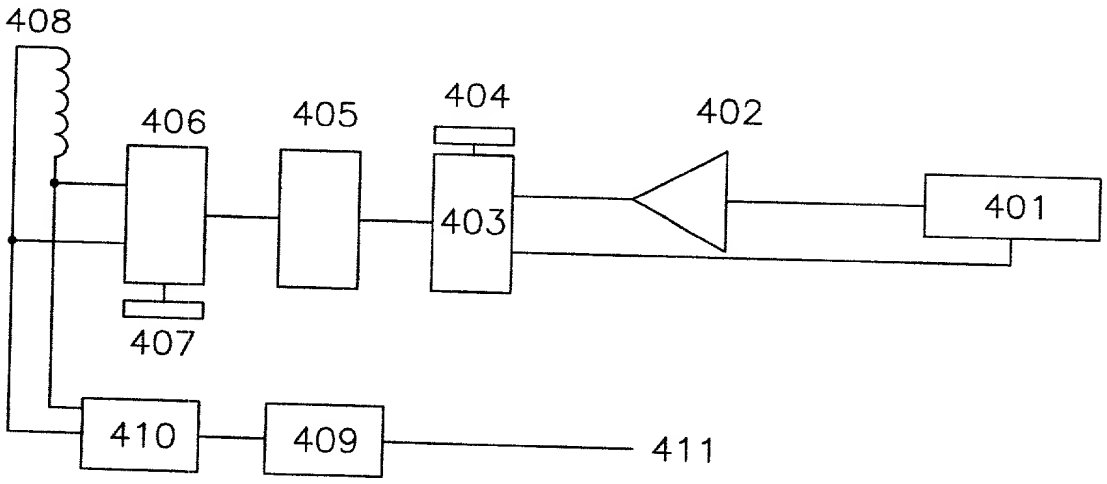
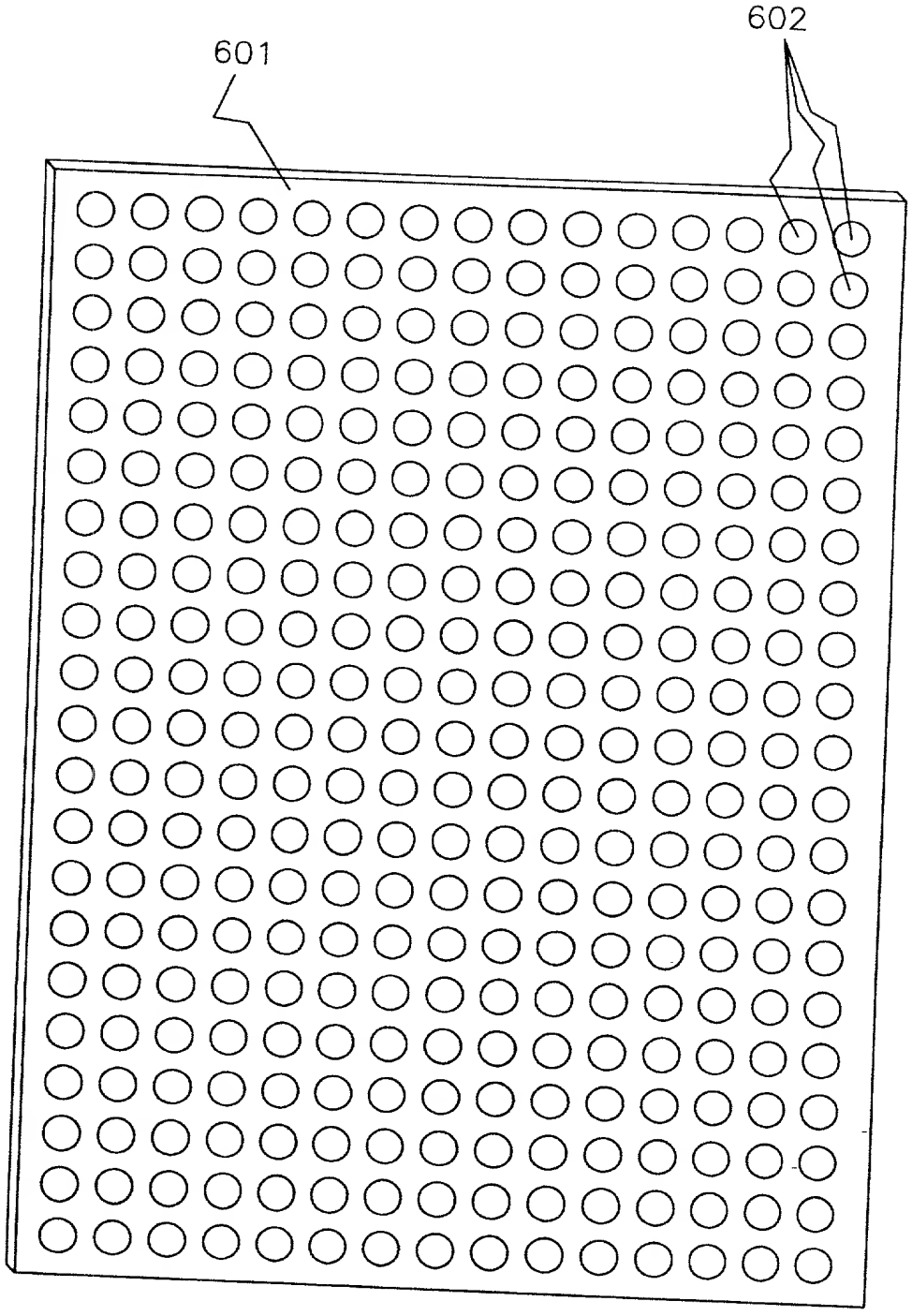


FIGURE 4

400



ELECTRODES ON SUBSTRATE

FIGURE 6a

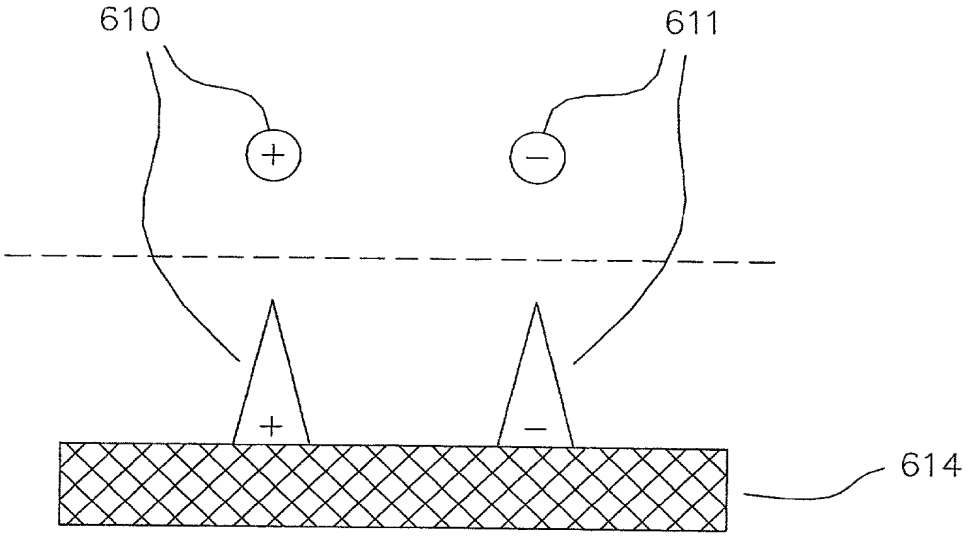


FIGURE 6b

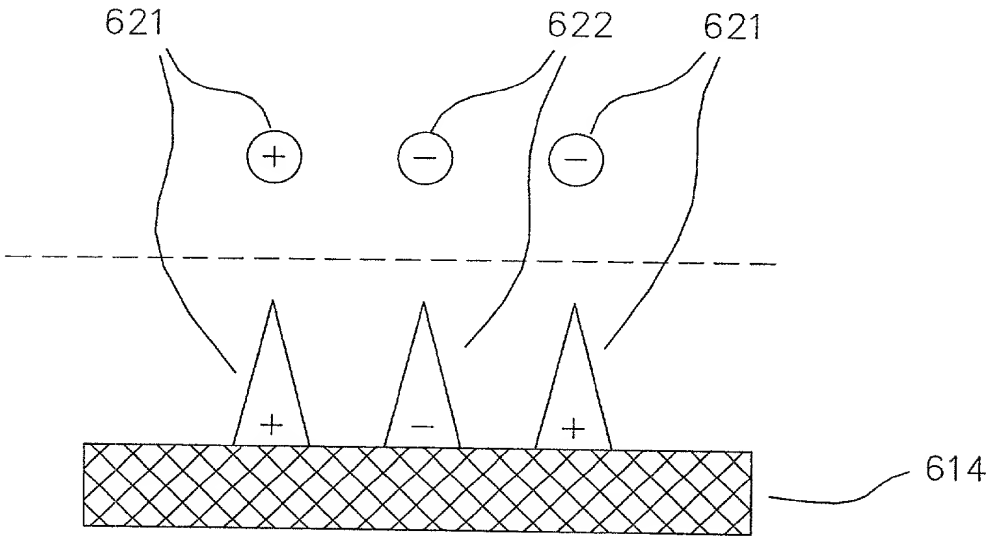
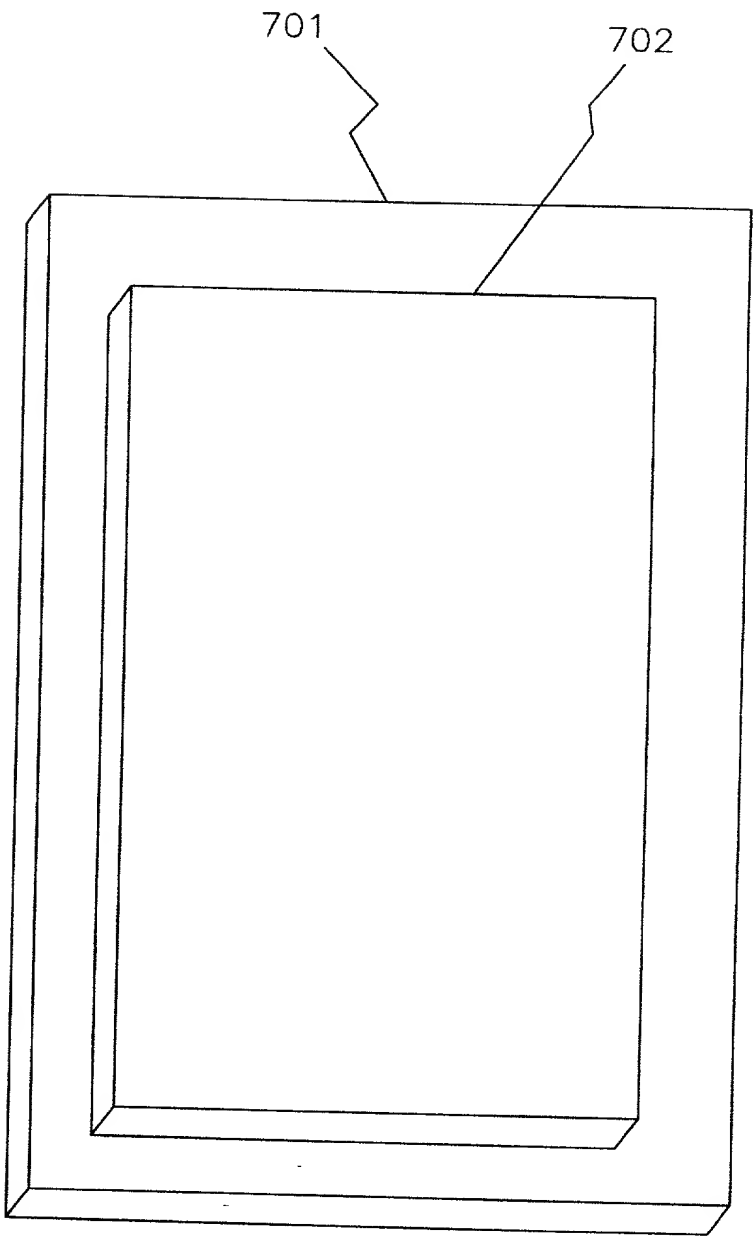


FIGURE 6c



INDIFFERENT ELECTRODE OF MONOPOLAR ELECTRODES

FIGURE 7

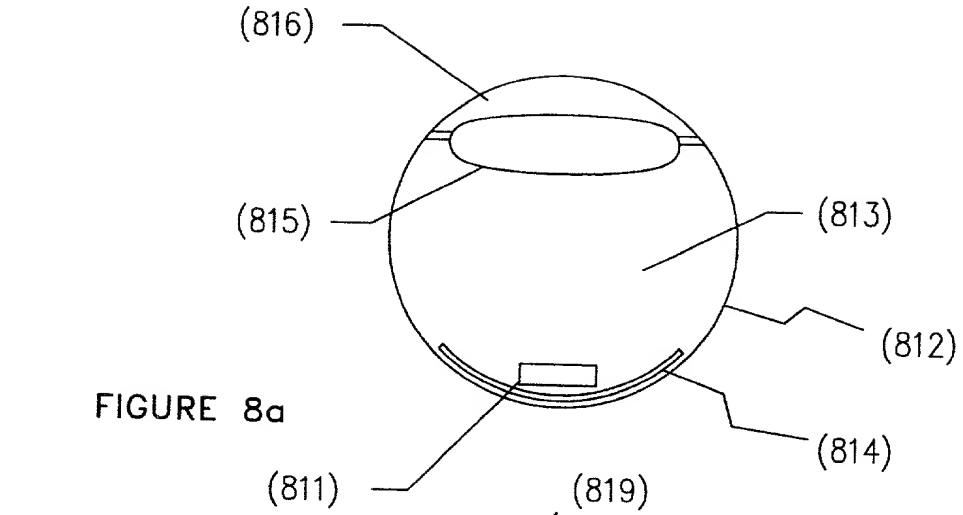


FIGURE 8a

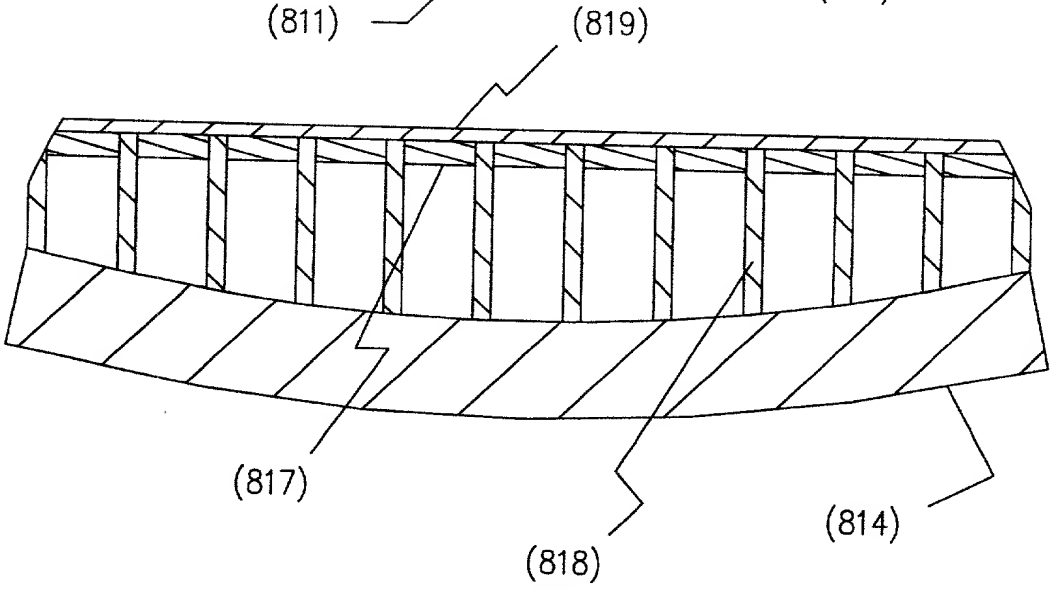


FIGURE 8b
EPIRETINAL ELECTRODES – RECESSED

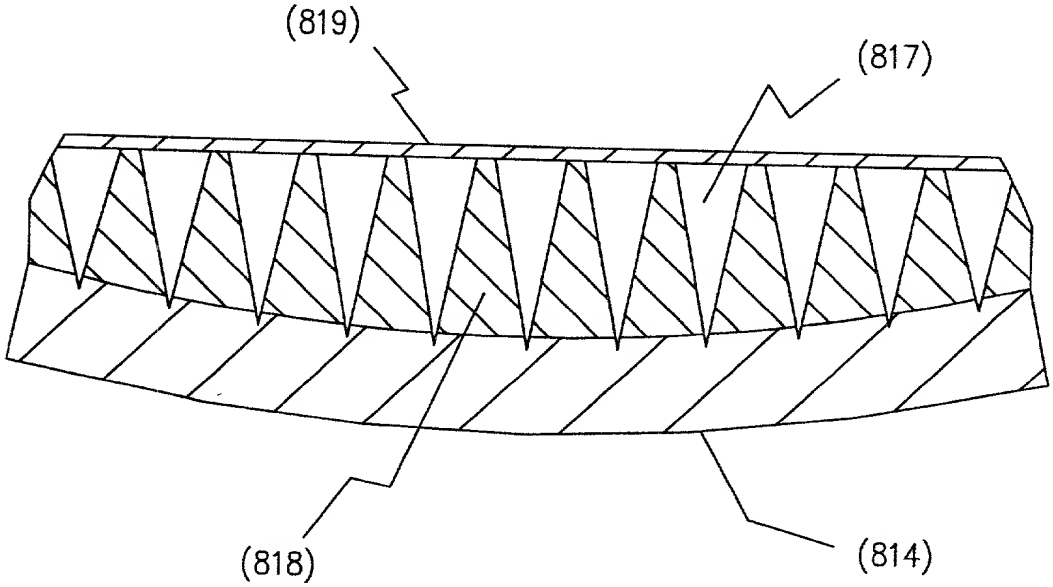


FIGURE 8c
EPIRETINAL ELECTRODES – PENETRATING

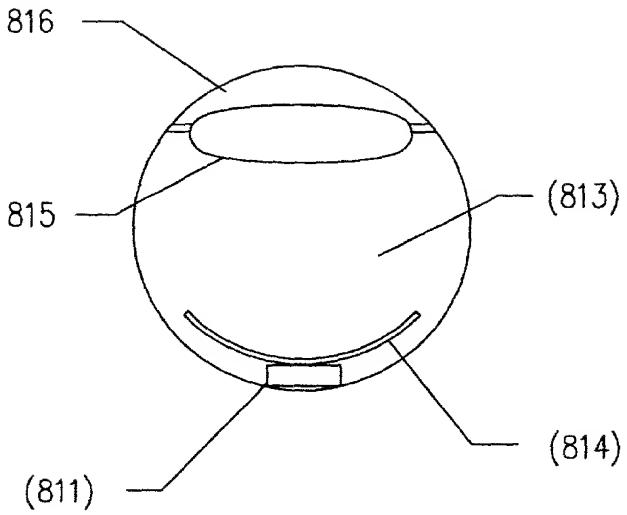


FIGURE 9a

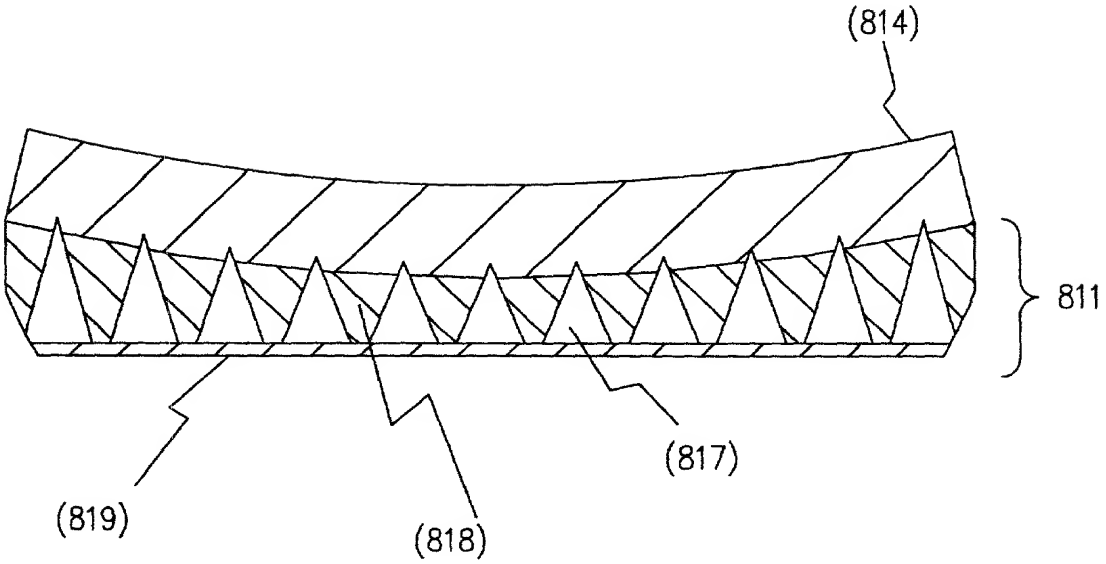
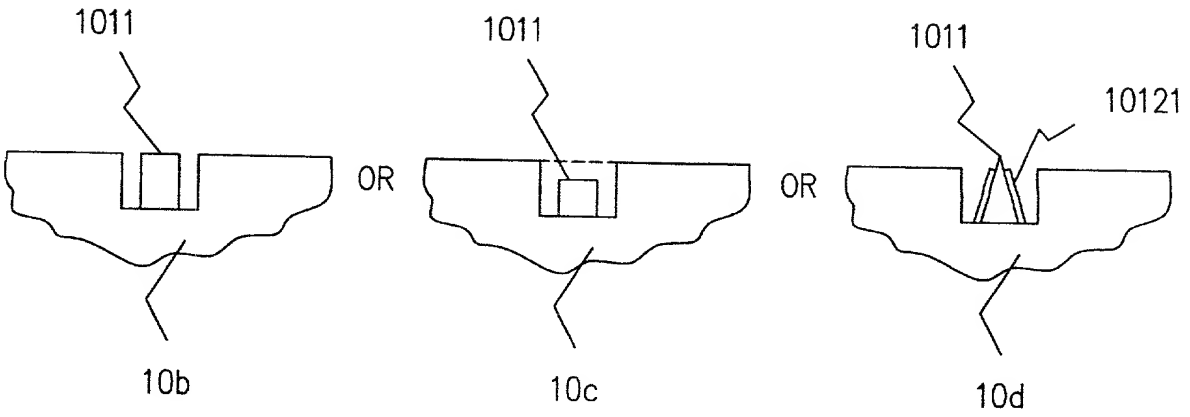
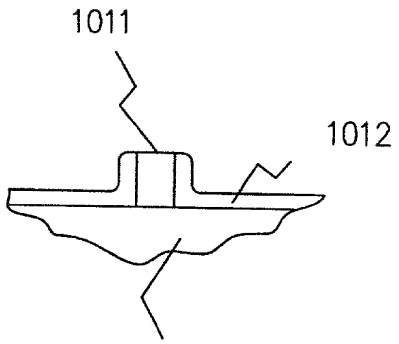
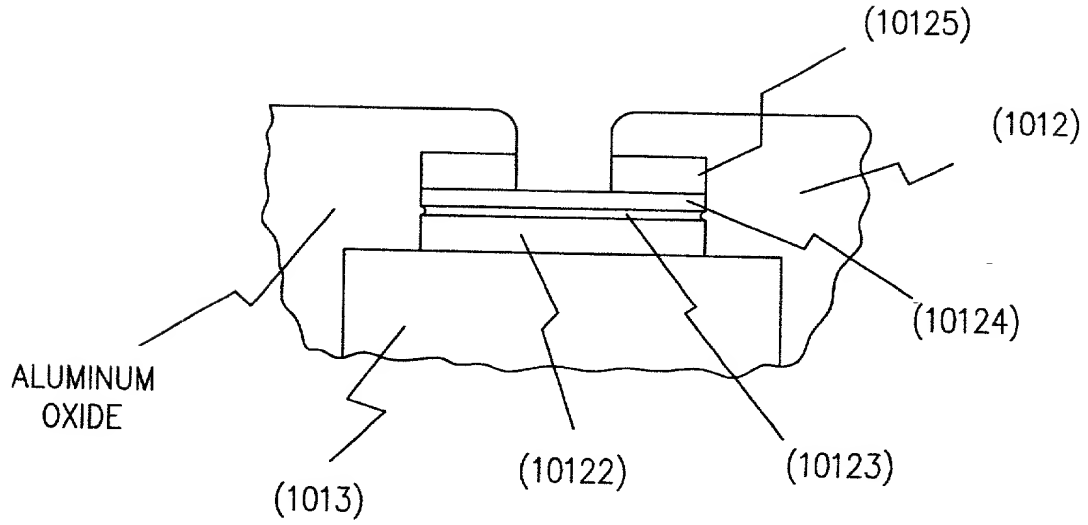


FIGURE 9b
SUBRETINAL ELECTRODES – PENETRATING





10a



10e

FIGURE 10

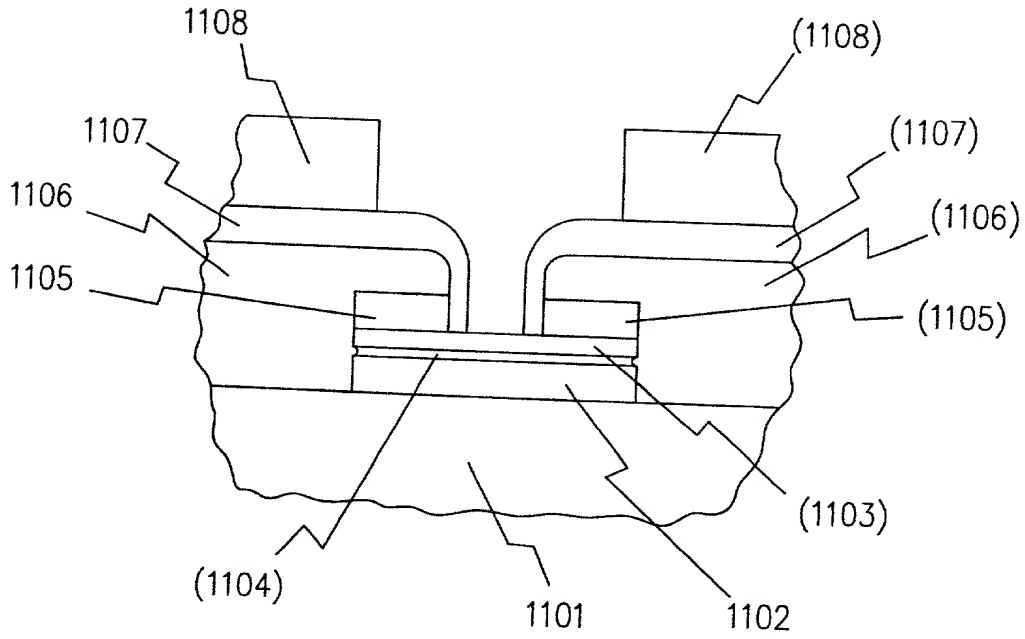


FIGURE 11a
ELECTRODES

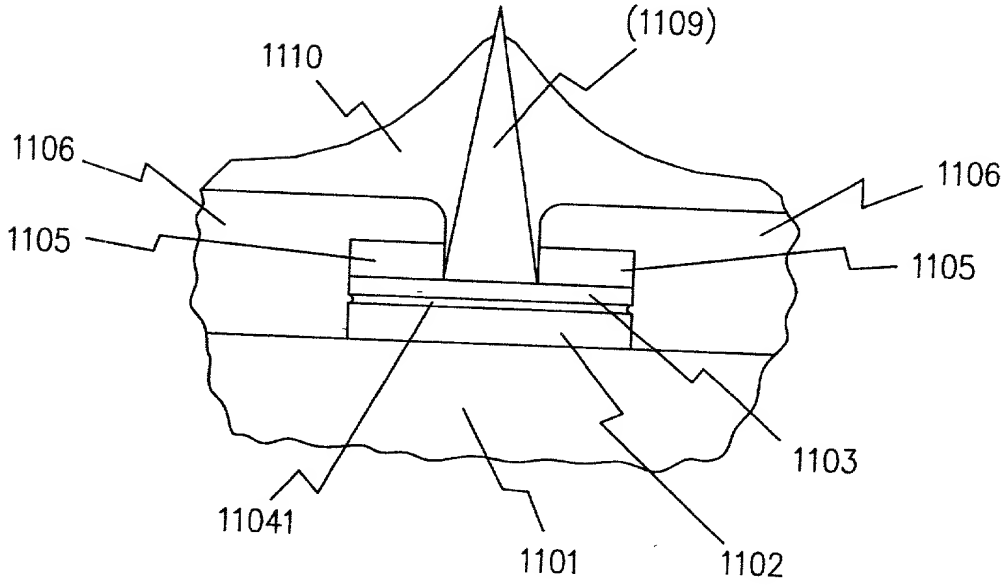


FIGURE 11b
ELECTRODES

FIGURE 11

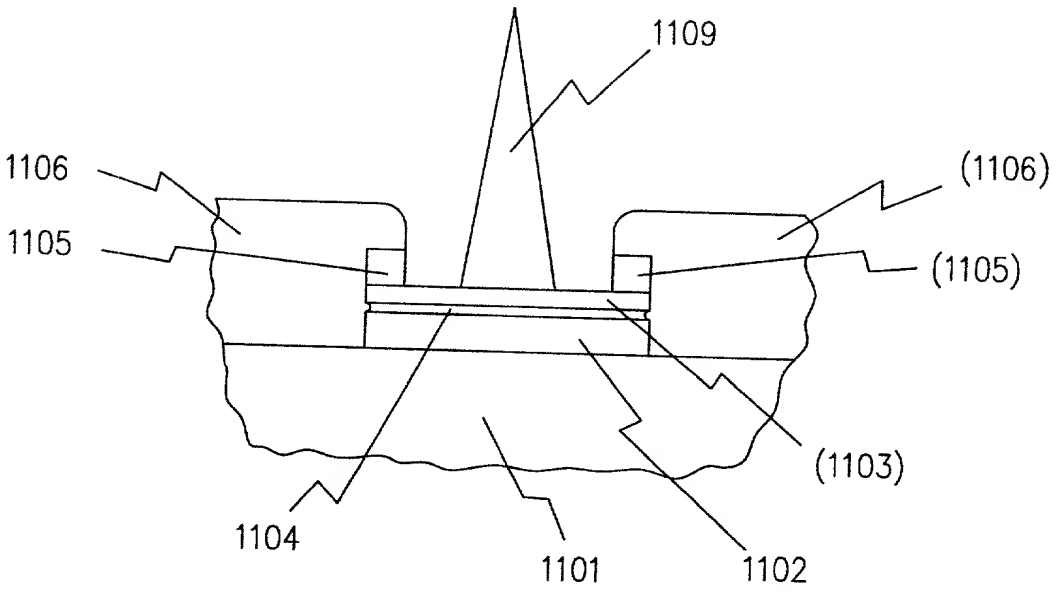


FIGURE 11c

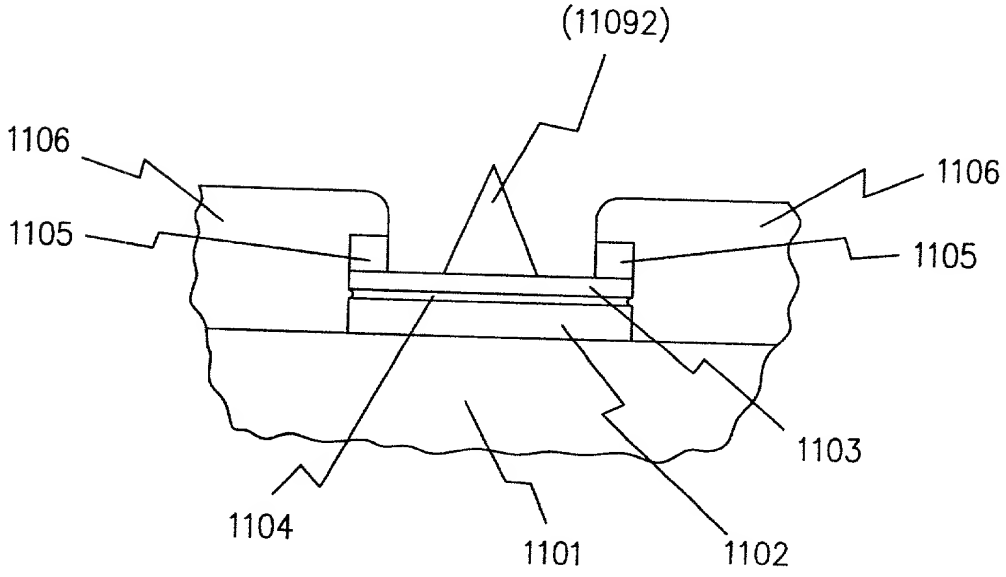


FIGURE 11d

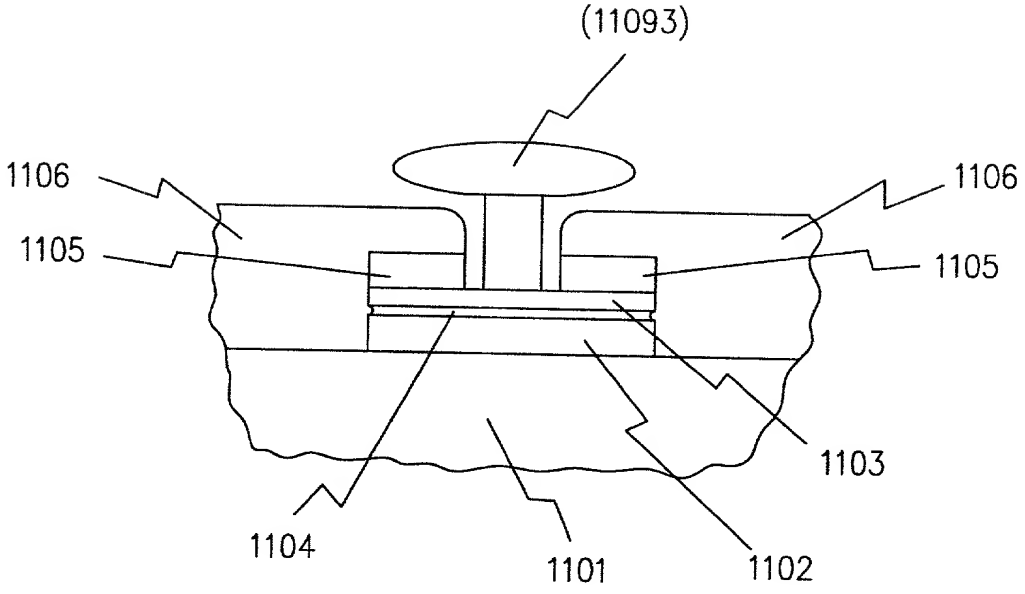
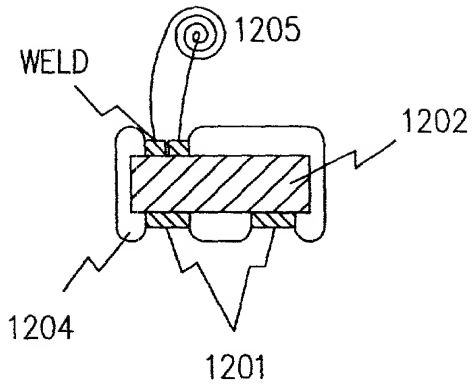
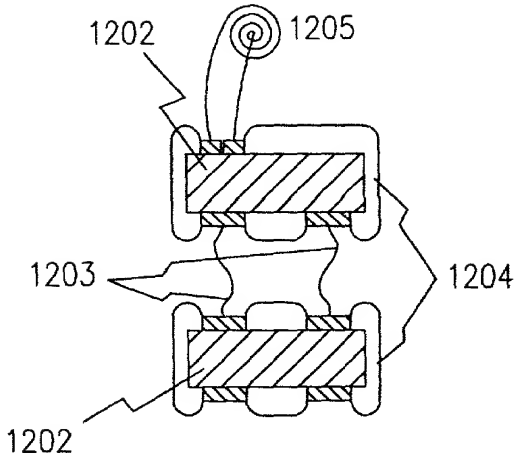


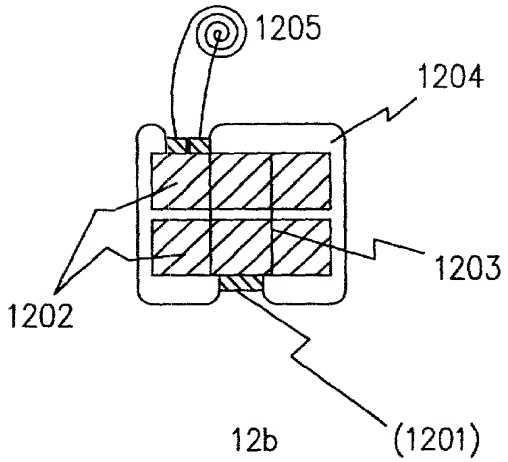
FIGURE 11e



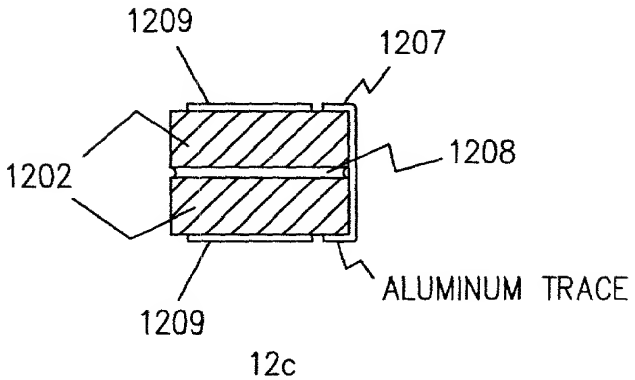
12a



12d



12b



12c

FIGURE 12
COIL AND WIRE ATTACHMENT TO SUBSTRATES AT ELECTRODE

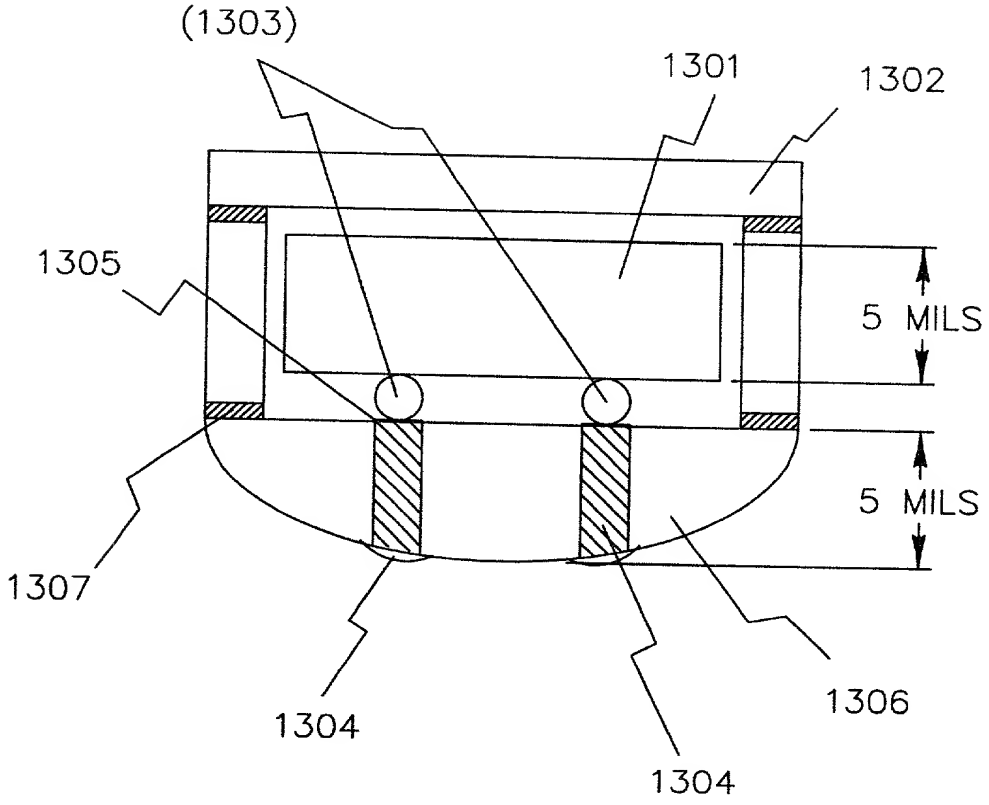


FIGURE 13
HERMETIC SEALING

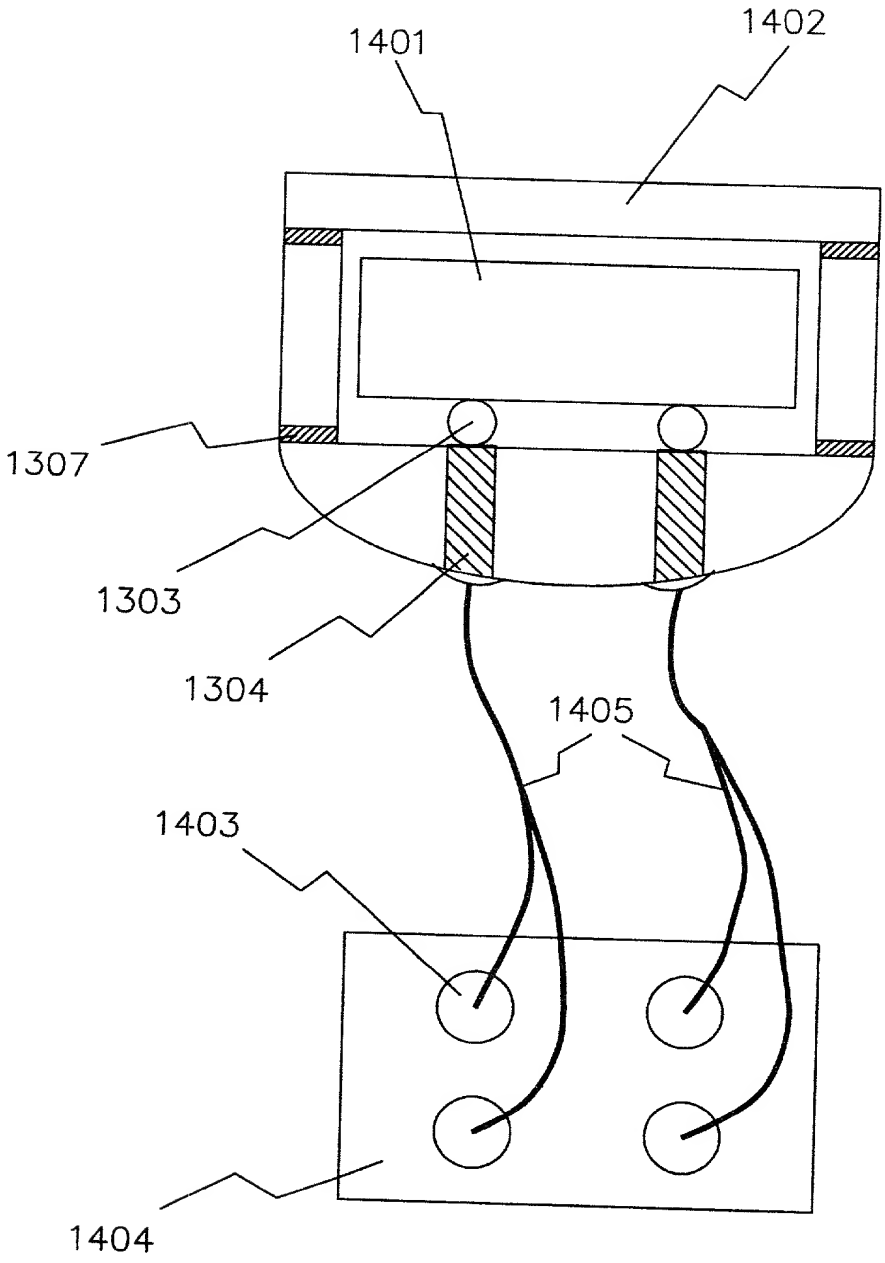


FIGURE 14

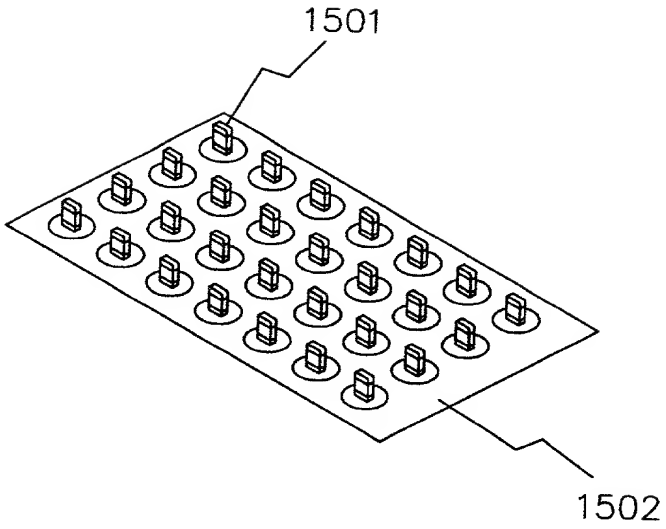


FIGURE 15

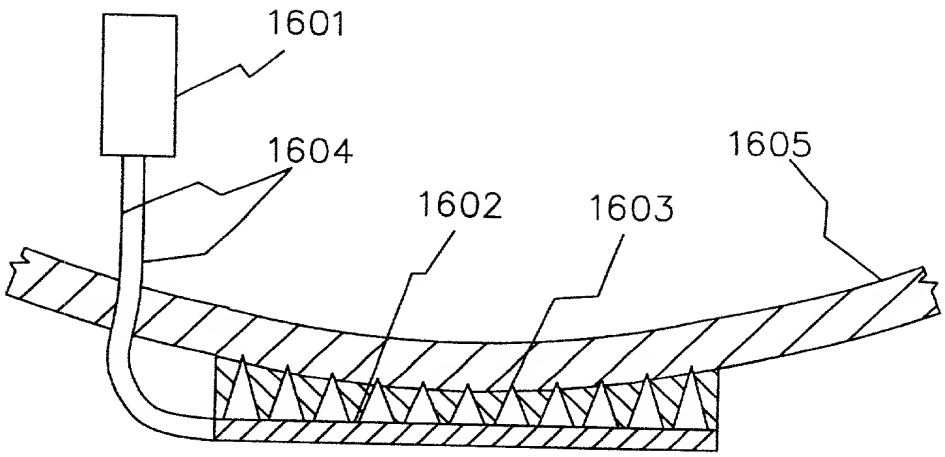


FIGURE 16a

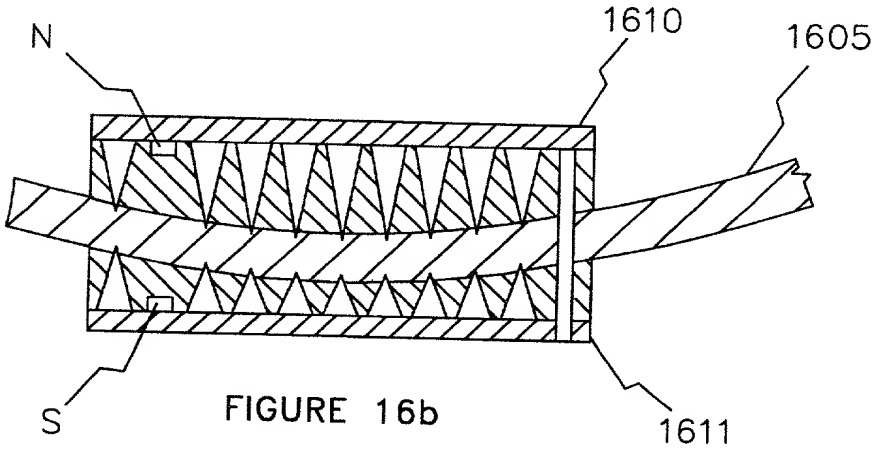


FIGURE 16b

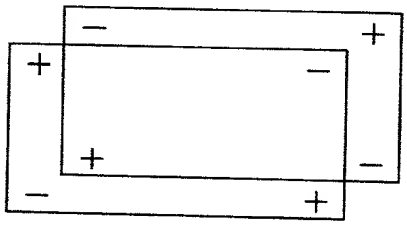


FIGURE 16c

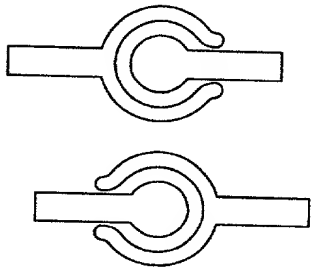


FIGURE 16d

PC PROGRAMMER

MAIN SCREEN

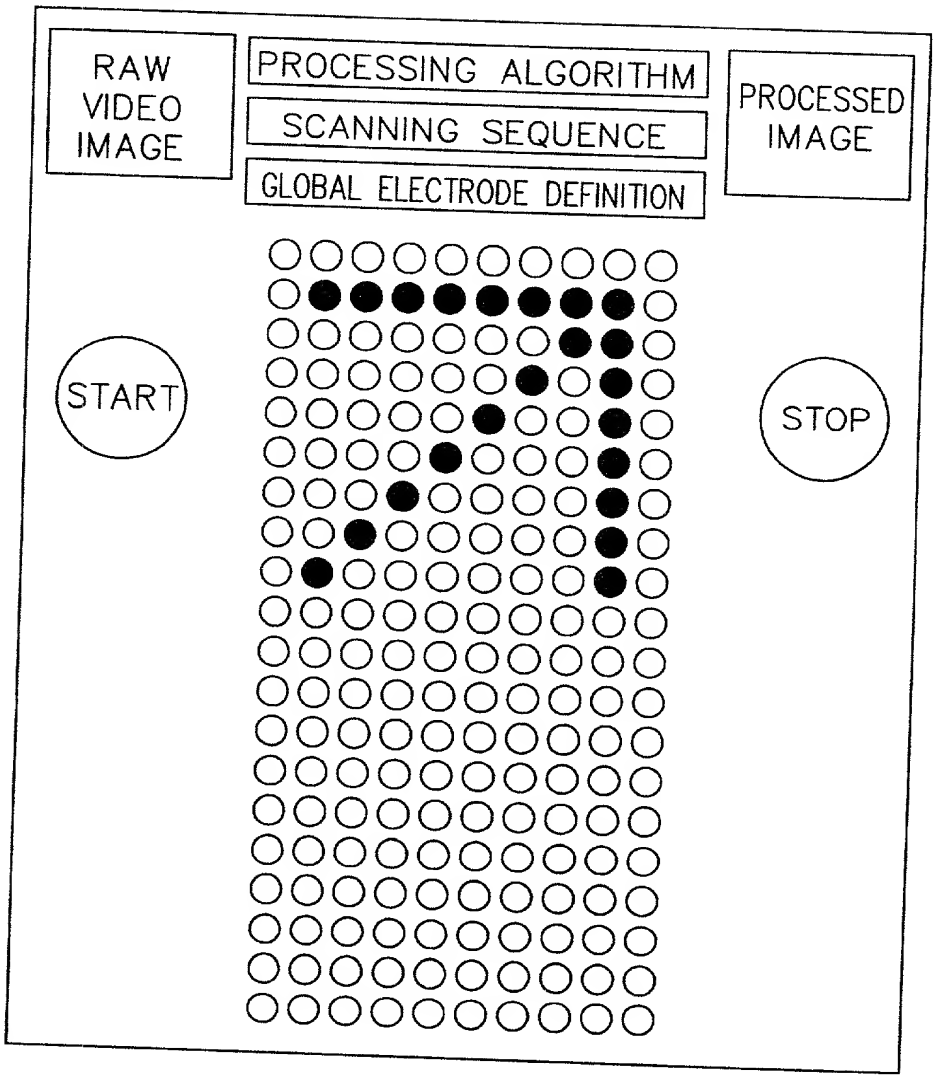


FIGURE 17a

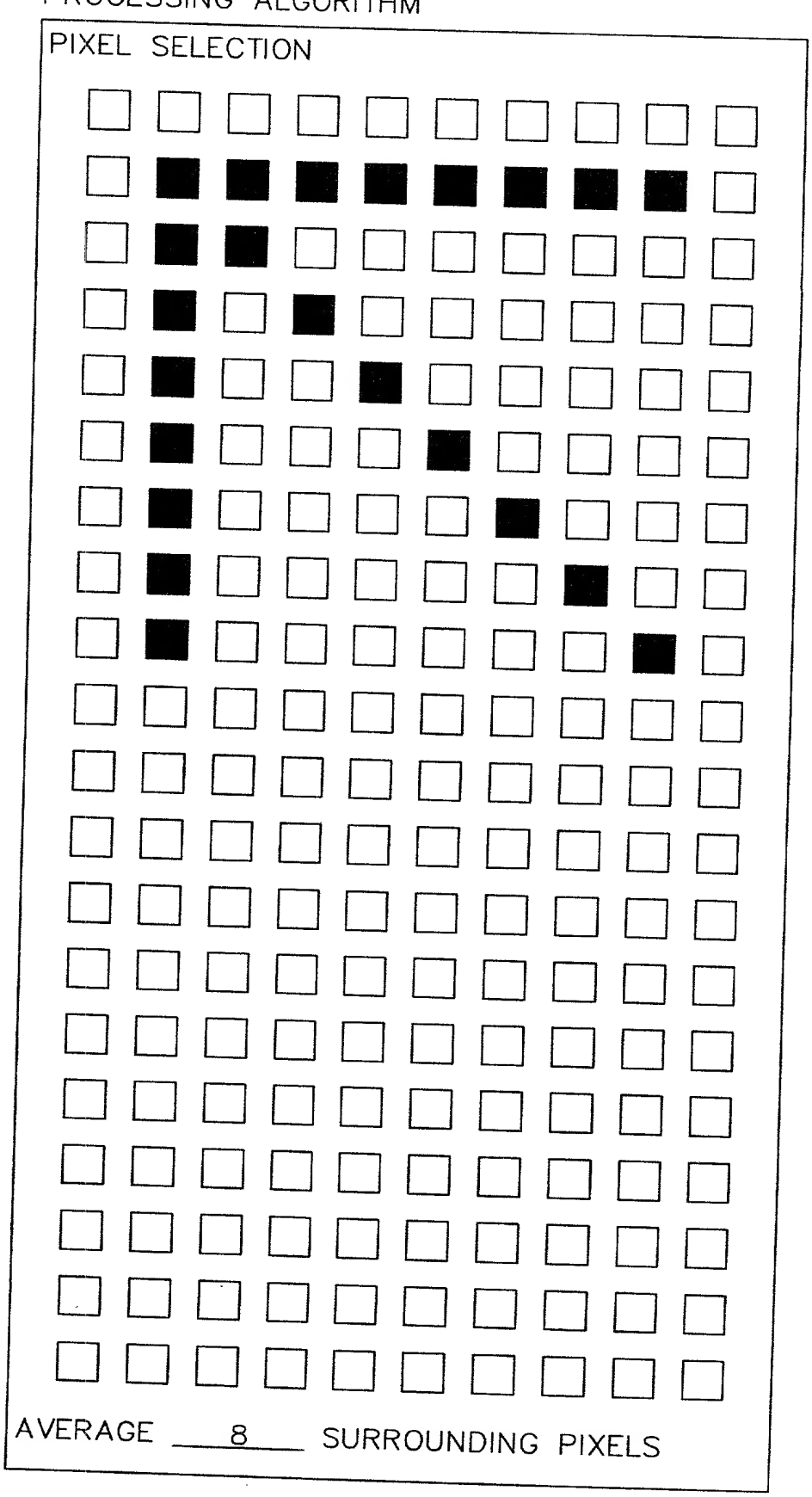
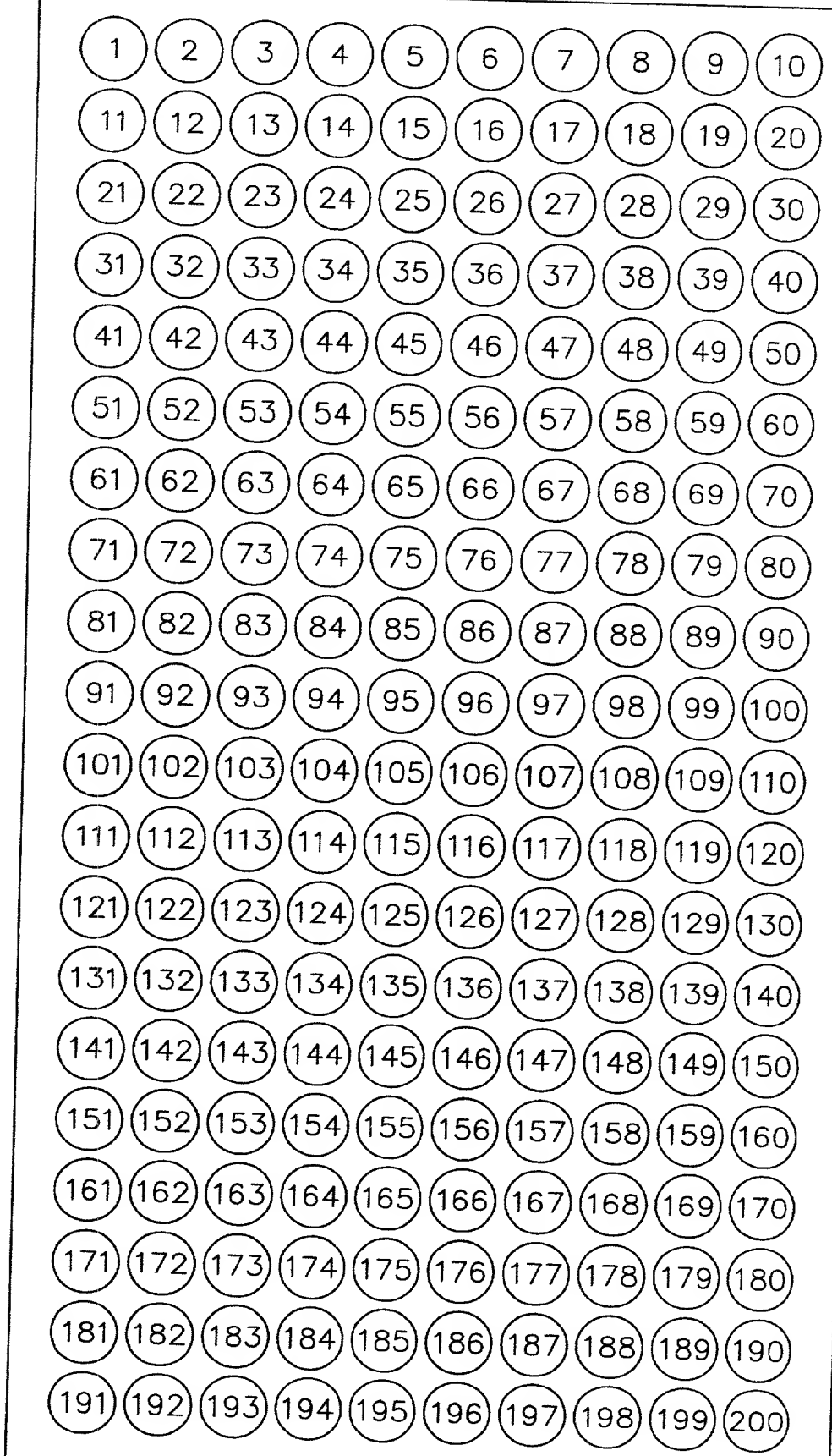

PROCESSING ALGORITHM
PIXEL SELECTION
AVERAGE 8 SURROUNDING PIXELS

FIGURA 17b

SCANNING SEQUENCE



PREDEFINED SEQUENCE A

FIGURE 17c

ELECTRODE PARAMETERS

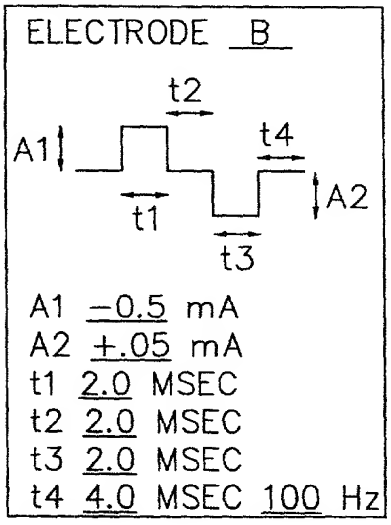


FIGURE 17d

GLOBAL ELECTRODE CONFIGURATION

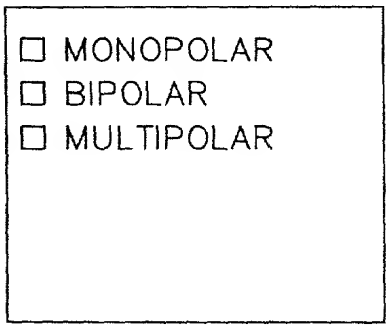


FIGURE 17e

BIPOLAR

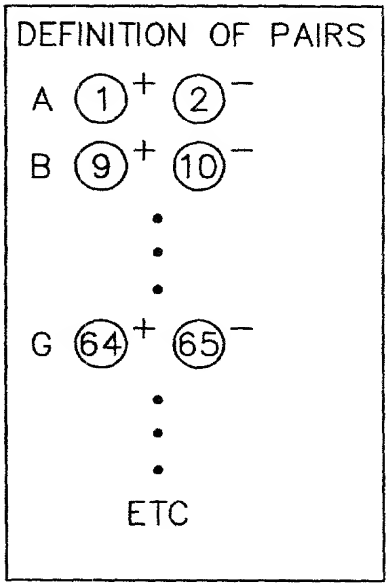


FIGURE 17f

MULTIPOLAR

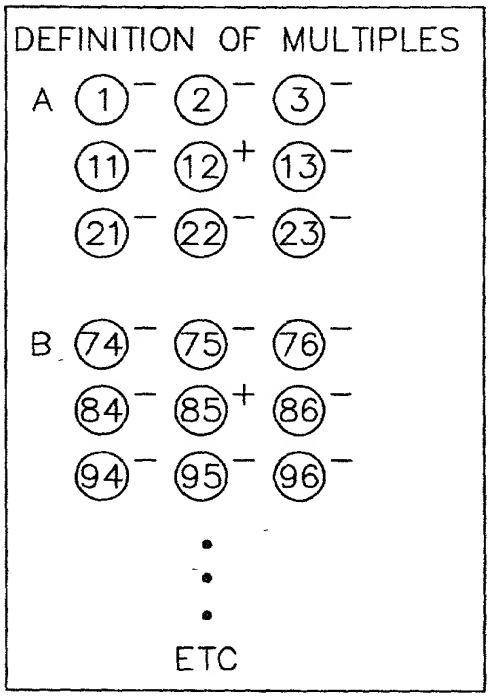


FIGURE 17g

PALM–SIZED TEST UNIT

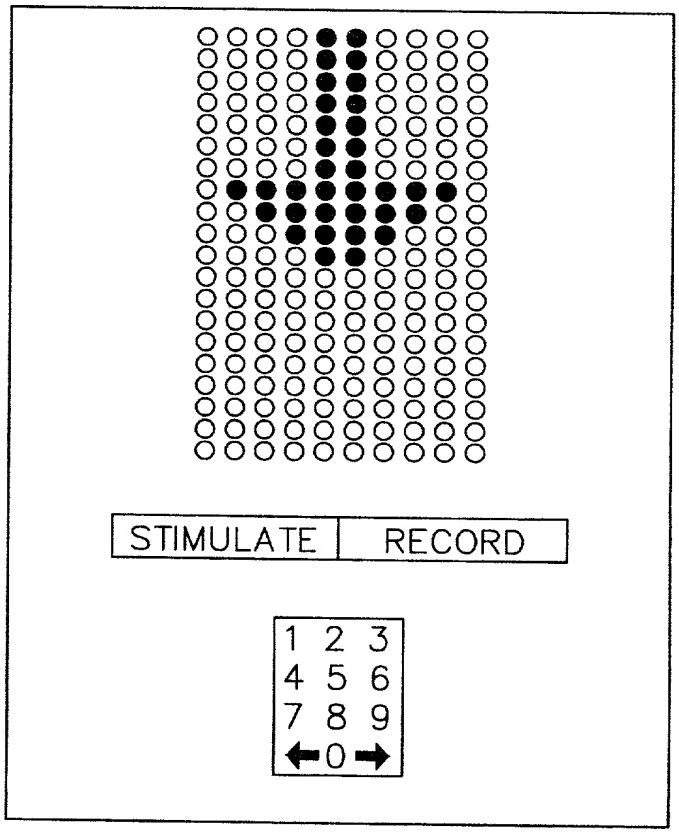
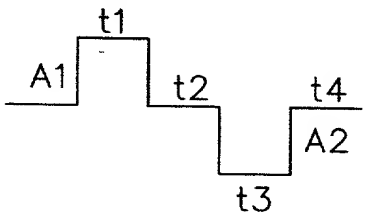


FIGURE 18a

STIMULATION SCREEN



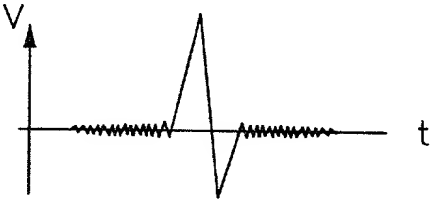
A1 −0.5 mA
A2 +0.5 mA
t1 2.0 MSEC
t2 2.0 MSEC
t3 2.0 MSEC
t4 4.0 MSEC
FREQ: 100 Hz

START STOP

FIGURE 18b

RECORDING SCREEN

RETINAL RECORDING
POST–STIMULUS



ELECTRODE IMPEDANCE:

10KΩ

FIGURE 18c

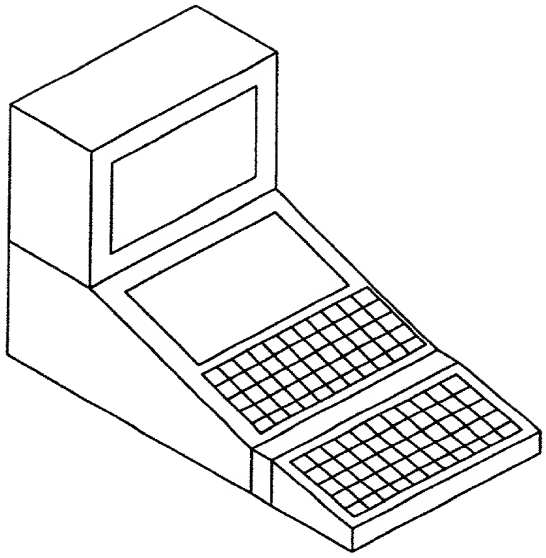


FIGURE 19a

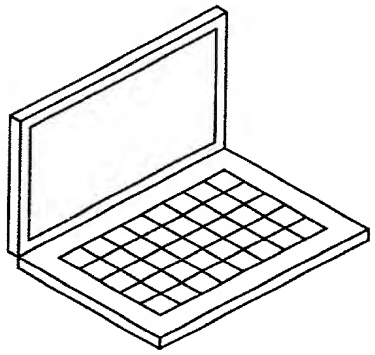


FIGURE 19b

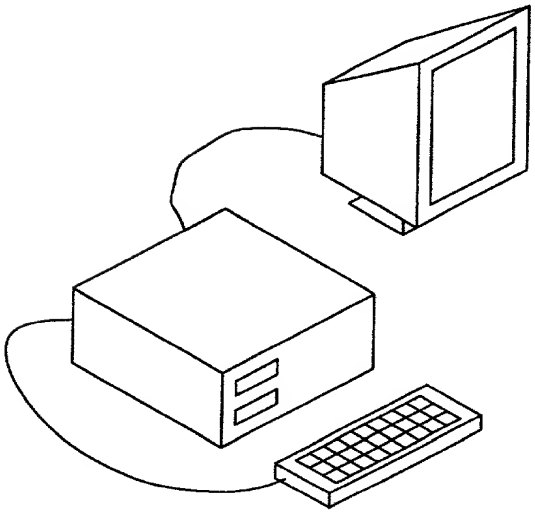


FIGURE 19c

PATIENT CONTROLLER

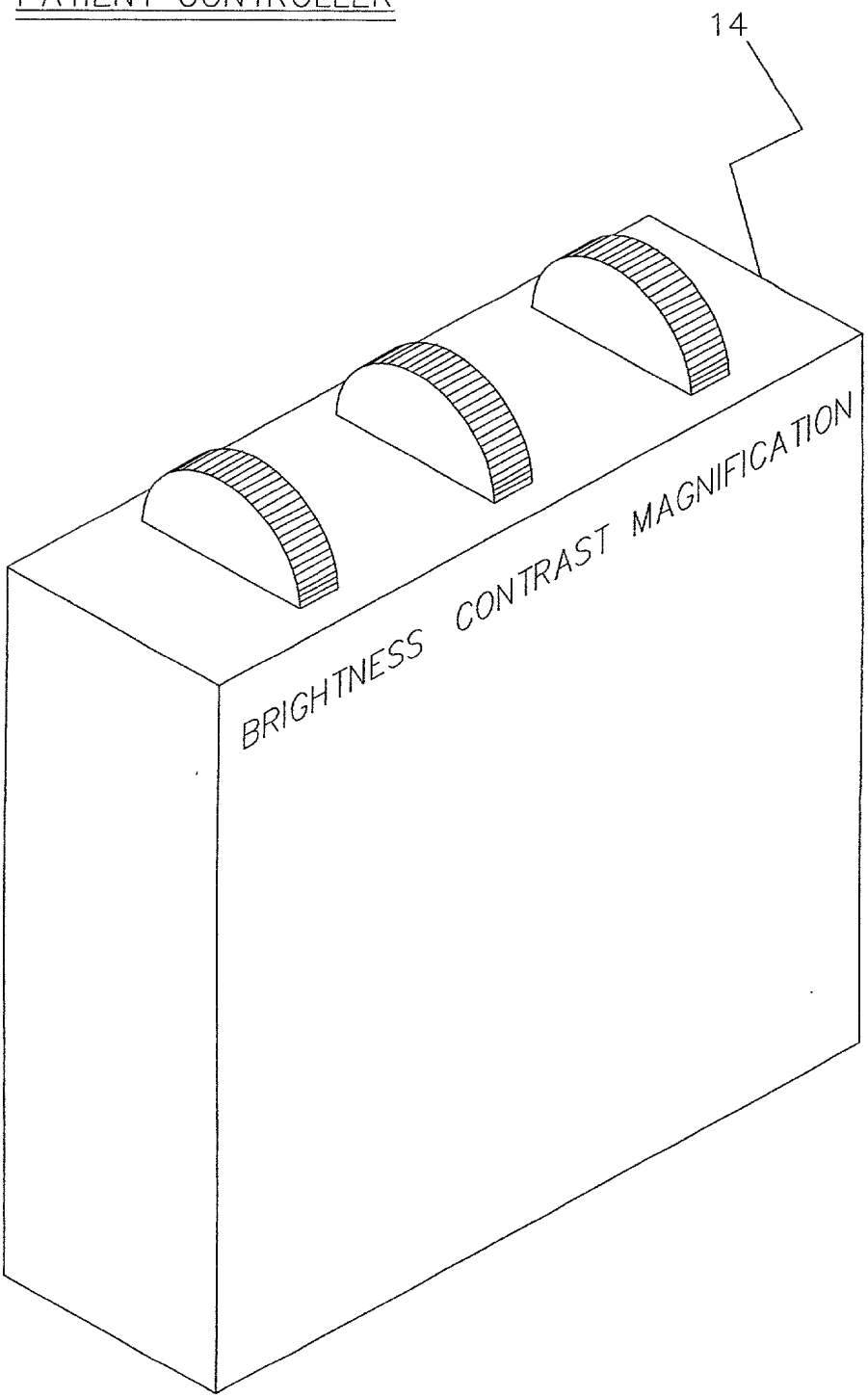


FIGURE 20